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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: December 15, at 9:00 a.m.
WHERE: Office of the Federal Register Conference Room, 800 North Capitol Street NW, Washington, DC (3 blocks north of Union Station Metro)
RESERVATIONS: 202–523–4538

NEW YORK, NY

WHEN: December 13, 9:30 a.m.–12:30 p.m.
WHERE: National Archives—Northeast Region, 201 Varick Street, 12th Floor, New York, NY
RESERVATIONS: 1–800–347–1997

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Reader Aids
Additional information, including a list of public laws, telephone numbers, and finding aids, appears in the Reader Aids section at the end of this issue.

Electronic Bulletin Board
Free **Electronic Bulletin Board** service for Public Law numbers, **Federal Register** finding aids, and a list of documents on public inspection is available on 202–275–1538 or 275–0920.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

RIN 3206–AG44

Prevailing Rate Systems; Abolishment of Cook, IL, Nonappropriated Fund Wage Area

AGENCY: Office of Personnel Management.

ACTION: Interim rule with request for comments.

SUMMARY: The Office of Personnel Management is issuing interim regulations to abolish the Cook, IL, nonappropriated fund (NAF) Federal Wage System wage area and add Cook County, IL, as an area of application to the Lake, IL, NAF wage area for pay-setting purposes. No employee's wage rate will be reduced as a result of this change.

DATES: This interim rule becomes effective on November 23, 1994. Comments must be received by December 23, 1994. Employees paid rates from the Cook, IL, NAF wage schedule will continue to be paid from that schedule until their conversion to the Lake, IL, NAF wage schedule effective on December 5, 1994.

ADDRESSES: Send or deliver comments to Donald J. Winstead, Acting Assistant Director for Compensation Policy, Personnel Systems and Oversight Group, U.S. Office of Personnel Management, Room 6H31, 1900 E Street NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Paul Shields, (202) 606–2848.

SUPPLEMENTARY INFORMATION: The Department of Defense recommended to the Office of Personnel Management that the Cook, IL, NAF wage area be abolished and that Cook County be assigned to another wage area. With the scheduled 1995 closing of the host installation, Naval Air Station, Glenview, IL, there will no longer be a local activity with the capability to do the survey. There will, however, still be about 44 NAF employees in Cook County.

The provisions of 5 CFR 532.219 list the following criteria for consideration when two or more counties are to be combined to constitute a single wage area:

(1) Proximity of largest activity in each county;

(2) Transportation facilities and commuting patterns; and

(3) Similarities of the counties in:

(i) Overall population;

(ii) Private employment in major industry categories; and

(iii) Kinds and sizes of private industrial establishments.

These criteria are discussed in turn below.

Lake County, IL, is much closer to Cook County than any other NAF wage area. Distances from Naval Air Station, Glenview, IL, to the host activities of the surrounding wage areas are as follows: Great Lakes Naval Training Center, Lake County, 35 km (22 miles); Rock Island Arsenal, Rock Island County, 285 km (177 miles); Fort Benjamin Harrison, Marion County, IN, 325 km (202 miles); and Scott Air Force Base, St. Clair County, 509 km (316 miles).

Transportation facilities and commuting patterns show Cook County to be much more closely associated with Lake County than the other NAF wage areas. Transportation facilities consist of interstate highways providing access from Glenview to each of the surrounding wage areas. An analysis of 1990 commuting patterns data indicates that 2,356,264 workers live in Cook County. Of these, 2,148,226 (91 percent) also work in Cook County. Of the counties under consideration, more Cook residents (39,585) commute to work in Lake County than any of the others. Only 211 Cook County residents commute to Marion County, IN, and none commute to Rock Island or St. Clair Counties.

The overall populations of Marion County (797,159) and Lake County (516,418) are much smaller than Cook County (5,105,067) but are more similar to Cook County than either Rock Island County (148,723) or St. Clair County (262,852).

In terms of private industry employment in major industry categories and kinds and sizes of private industry establishments, Cook County more closely resembles Marion County, followed by Lake County, and least resembles Rock Island and St. Clair Counties.

In summary, proximity, transportation facilities, and commuting patterns strongly favor assigning Cook County to the Lake, IL, NAF wage area. In terms of population, employment, and industry, none of the candidate areas is very similar to Cook County. However, Marion County, with the largest population and employment of the areas reviewed, is the most similar, and Lake County is the next most similar. On balance, evaluation under the criteria favor the definition of Cook County to the Lake, IL, NAF wage area.

The Federal Prevailing Rate Advisory Committee reviewed this recommendation and by consensus recommended approval.

Employees paid rates from the Cook, IL, NAF wage schedule will be converted to the Lake, IL, NAF wage schedule on December 5, 1994, the date the current Cook, IL, NAF wage schedule would have been superseded were the Cook wage area not abolished.

Pursuant to 5 U.S.C. 553(b)(3)(B), I find that good cause exists for waiving the general notice of proposed rulemaking. Also, pursuant to section 553(d)(3) of title 5, United States Code, I find that good cause exists for making this rule effective in less than 30 days. The notice is being waived and the regulation is being made effective in less than 30 days because preparations for the October 1994 Cook survey must otherwise begin immediately.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they affect only Federal agencies and employees.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

U.S. Office of Personnel Management.

James B. King,

Director.

Accordingly, OPM is amending 5 CFR part 532 as follows:

PART 532—PREVAILING RATE SYSTEMS

1. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

Appendix D to Subpart B of Part 532 [Amended]

2. In Appendix B to the subpart B, the listing for the State of Illinois is amended by removing the entry for Cook.

3. Appendix D to subpart B is amended by removing the wage area list for Cook, Illinois, and by revising the list for Lake, Illinois, to read as follows:

Appendix D to Subpart B of Part 532—Nonappropriated Fund Wage and Survey Areas

* * * * *

Illinois

Lake

Survey area

Illinois:
Lake

Area of application. Survey area plus:

Illinois:
Cook [1]
Wisconsin:
Dane
Milwaukee

[1] Effective date December 5, 1994.

* * * * *

[FR Doc. 94–28856 Filed 11–22–94; 8:45 am]
BILLING CODE 6325–01–M

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5 CFR Part 890

RIN 3206–AF74

Federal Employees Health Benefits Program; Miscellaneous Changes

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing final regulations which implement a number of miscellaneous changes to the Federal Employees Health Benefits (FEHB) Program. The changes will improve the administration of the FEHB Program and result in better service to enrollees.

EFFECTIVE DATE: December 23, 1994.

FOR FURTHER INFORMATION CONTACT: Robert G. Iadicicco, (202) 606–0191.

SUPPLEMENTARY INFORMATION: On May 10, 1994, OPM issued proposed regulations in the Federal Register (59 FR 24062) to clarify the last day of Open Season; give Federal retirement systems staffs the discretion to allow annuitants to make FEHB coverage changes by other methods, such as telephone requests; allow legally separated employees and annuitants covered as family members under their spouses' FEHB enrollment to enroll in FEHB for self only or self and family coverage; extend to employees whose FEHB enrollment terminated when they entered on duty in a uniformed service and who retire on an immediate annuity from their Federal civilian position while on such duty the option of reinstating FEHB coverage upon retirement; permit annuitants, whose entire annuity or compensation has been waived or suspended, to pay FEHB premiums directly to their retirement system or the Office of Workers' Compensation Programs for any period of wavier or suspension which is three months or more; require agencies to counsel employees entering leave without pay (LWOP) status, or whose pay is insufficient to cover their FEHB premium payments, of the options of continuing or terminating their FEHB coverage, and if continuing, of paying premiums directly on a current basis or incurring a debt to be withheld from future salary.

These final regulations cover all of the changes in the proposed regulations except the requirement that agencies counsel employees entering LWOP or whose pay is insufficient to cover their FEHB premium payments. We will issue separate interim regulations on that change.

We received comments from two FEHB plans, two Federal agencies, and one retiree organization. One commenter agreed that the proposed changes will result in better service to enrollees and considered the change to allow annuitants to make FEHB coverage changes by telephone especially significant. The commenter recommended that retirement systems establish a dedicated telephone number, or a system that will record FEHB coverage change requests. OPM is doing this and more. OPM's Office of Retirement Programs (ORP) administers the Civil Service Retirement System and the Federal Employees Retirement System. ORP's Retirement Information Office (RIO) phone system at (202) 606–0500 will have a voice mail box dedicated to recording FEHB coverage change requests. RIO staff will either make the coverage change requested or call the annuitant to obtain additional information required before making the change. In addition, ORP will not limit annuitants to calling RIO to request a coverage change. At first, both RIO and ORP's Insurance Services Branch will be authorized to take the calls and make the changes. Eventually, all staff in ORP will accept requests and process coverage changes.

The commenter also recommended that other retirement systems allow their annuitants to make FEHB coverage changes by telephone and follow the OPM "model" in order to minimize the confusion that would occur if other retirement systems used a different model. Our intention is to give retirement systems the discretion to accept alternatives to a properly completed health benefits registration form (SF 2809), but not require the retirement systems to do so. Our reasoning is that it is the responsibility of each retirement system to determine how to best serve their annuitants. OPM has determined that our annuitants are best served by allowing them to make FEHB coverage by telephone. Other retirement systems may decide, based on their current capabilities or other factors, not to allow telephone requests. Of course, we are more than willing to share our knowledge and procedures with other retirement systems who want to follow our "model."

Three commenters expressed concern that allowing telephone requests increases the possibility of unauthorized coverage changes by someone other than the annuitant, and will result in misunderstandings between the annuitant and OPM. Two commenters suggested that the retirement system send a notice of the coverage change to the annuitant. OPM agrees with this suggestion and is revising the regulations to require the retirement system to promptly give annuitants written notification of the change in coverage. ORP already follows this requirement by automatically generating notices of FEHB changes to provide annuitants with an early opportunity to reverse erroneous or unauthorized changes.

One commenter suggested as an alternative to telephone requests we allow annuitants to submit a written request to OPM at a post office box number specifically designated for health benefits requests or to fax their requests. OPM already has a post office box number specifically designated for health benefits requests. In contrast to a telephone call, a post office box does not eliminate the time is takes for the request to be delivered to OPM. The faxing of requests does save time, but most annuitants do not have convenient, inexpensive access to a fax machine. However, under these regulations retirement systems have the authority to accept faxed requests for coverage changes and OPM will do so.

One commenter was concerned that telephone requests would not be processed by retirement system staff because of the lack of a written document. The commenter suggested allowing changes by letter because it would provide written documentation of the request. We agree that a retirement system must be confident that telephone requests will be processed and be processed accurately before the retirement system accepts telephone requests. We are confident that ORP will accurately process telephone requests for three reasons. First, ORP staff already have a great deal of experience handling telephone requests for other changes, such as changes of address. Second, ORP staff already have developed procedures to follow when they handle telephone requests for FEHB coverage changes. Third, in the rare case the telephone request is incorrectly processed or not processed at all, the annuitant will soon become aware of the error through the retirement system's notice of the coverage change, or the lack of notice and the health benefits enrollment data included in their next monthly annuity payment statement.

Two commenters stated that it is extremely important for the retirement system to obtain all the pertinent information from the annuitant and accurately communicate the information to the FEHB plans. One of the commenters stressed that accurate communication of dependent information is especially important. The other commenter recommended that the retirement system staff person complete a SF 2809 while taking the request. We agree that when taking a telephone request the retirement system staff needs to collect and communicate to the FEHB plans the same information they provide for all other coverage changes. Therefore, we are revising the proposed regulations by specifying that alternative methods of making FEHB coverage changes, such as telephone requests, must transmit to the health benefit plans the information they require before accepting an enrollment. Because OPM uses a more advanced method to transmit information to the plans, there is no need for OPM staff to prepare a SF 2809 when taking a telephone request. However, for retirement systems who use the SF 2809 to transmit information to the plans, filling out the SF 2809 when taking the telephone request is a practice that should be strongly considered.

One commenter stated that allowing OPM retirement system staff to make coverage changes based on telephone requests may cause problems in tracking coverage changes. We are confident tracking problems will not occur because ORP has had for many years an on-line tracking system to record all coverage changes. The tracking system creates an FEHB change history file for each annuitant.

One commenter responded to our statement in the supplementary information section of the proposed regulations that most employees work near the office responsible for their FEHB actions by noting a significant percentage of their agency's employees work at remote sites. The commenter believes that there are other agencies with similar workforces and requested OPM to make this logistical situation an important consideration in its future policy and program planning. OPM has always been aware that certain agencies, because of their mission, have a significant percentage of employees at remote locations. We are also keenly aware of the need to increase the efficiency of Federal personnel operations through automation. Consequently, we are considering a regulatory change that would allow agencies to automate their FEHB enrollment processing and invite all interested agencies to contact us.

One commenter concurred with the change allowing a legally separated employee or annuitant covered as a family member under his or her spouses' FEHB enrollment to enroll in FEHB for self only or self and family coverage. The commenter also asked whether this change means an employee with a self and family enrollment can drop the coverage of their separated spouse, if the spouse is ineligible to enroll or decides not to enroll for FEHB coverage. An employee may switch to self only coverage at any time and in that way drop the coverage of their separated spouse. However, unless a separated spouse has his or her own enrollment, he or she remains covered under the employee's self and family enrollment.

We received three comments discussing the fact that while the regulations would allow the dual enrollment of legally separated employees or annuitants, they did not allow a person to be covered and receive benefits under more than one enrollment. The regulations require each enrollee to notify the insurance carrier of the names of family members covered under his or her enrollment that are not covered under the other enrollment.

One commenter wanted to know the employing office's responsibility for ensuring that the employee notifies the insurance carrier of covered family members. An employing office, when it becomes aware or strongly suspects that both members of a legally separated couple are enrolled or enrolling in the FEHB Program and at least one has a self and family enrollment, is responsible for informing the employee that he or she must notify the insurance carrier of the family members covered under the enrollment that are not covered under the other enrollment.

One commenter strongly recommended that employing offices should include the carrier code and the family members covered under the enrollments of both legally separated spouses in the remarks section of the SF 2809. The commenter believes this will assist the FEHB carriers to contact other carriers when necessary. We think this is a good idea and recommend offices that send the SF 2809 to carriers follow this practice whenever possible and offices that do not send the SF 2809 find another method to send carriers this information.

One commenter was concerned about the employing office's responsibility in cases where a person is covered and receives benefits under more than one enrollment because the employee did not notify the carrier. Carriers will contact employing offices directly to resolve any dual coverage cases they discover. Employing offices are responsible for assisting carriers in resolving these cases. Employing offices are also responsible for informing carriers when they become aware a person is being covered and receiving benefits under more than one enrollment.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they primarily affect Federal employees, annuitants, and former spouses.

List of Subjects in 5 CFR Part 890

Administrative practice and procedure, Government employees, Health facilities, Health insurance, Health Professions, Hostages, Iraq, Kuwait, Lebanon, Reporting and recordkeeping requirements, Retirement.

U.S. Office of Personnel Management.

James B. King,

Director.

Accordingly, OPM is amending 5 CFR part 890 as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

1. The authority citation for part 890 is revised to read as follows:

Authority: 5 U.S.C. 8913; § 890.803 also issued under 50 U.S.C. 403p, 22 U.S.C. 4069c and 4069c–1; subpart L also issued under sec. 599C of Pub. L. 101–513, 104 Stat. 2064, as amended.

2. In § 890.101, the definition of *Register* is revised to read as follows:

§ 890.101 Definitions; time computations.

* * * * *

Register means to file with the employing office a properly completed health benefits registration form, either electing to be enrolled in a health benefits plan or electing not to be enrolled. Retirement systems may accept alternative methods, such as telephone requests, in substitution of a properly completed health benefits registration form. Alternative methods must transmit to the health benefits plans the information they require before accepting an enrollment. In addition, for enrollments and cancellations to be valid, the signature of the requesting individual must be on the request, or on a form from the retirement system to the requesting individual giving notice of the enrollment or cancellation. For changes of enrollment, the signature of the requesting individual is not required but the retirement system must promptly give to the requesting individual written notice of the change of enrollment. *Register to enroll* means to register an election to be enrolled. *Enrolled* means a valid registration form has been accepted by the employing office, or an alternative method has been accepted by the retirement system, and the enrollment in a health benefits plan approved by OPM under this part has not been terminated or cancelled.

* * * * *

§ 890.301 [Amended]

3. In § 890.301, paragraph (c) is amended by removing "§ 890.304(a)(4)" and adding in its place "§ 890.304(a)(5)"; paragraph (d)(1) is amended by removing "through the Friday of the first full work-week in December" and adding in its place "through the Monday of the second full workweek in December".

4. In § 890.302, paragraph (a)(2) is revised, and paragraph (a)(3)(i) is amended by adding the words "or legally separated" after the word "divorced", to read as follows.

§ 890.302 Coverage of family members.

(a) * * *

(2) *Dual enrollment—spouse.* (i) To protect the interests of the children, an employee or annuitant may enroll in his or her own right in a self and family enrollment even though his or her spouse also has a self and family enrollment. Generally, such dual enrollments are permitted only where two employees or annuitants are married, each with children from prior marriages who do not live with them, or are legally separated, with each spouse retaining custody of his or her own children by a prior marriage. To ensure that no person receives benefits under more than one enrollment, each enrollee must tell the insurance carrier which family members are covered under his or her enrollment. These individuals are not covered under the other enrollment.

(ii) To protect the interests of legally separated Federal employees, annuitants and their children, a legally separated employee or annuitant may enroll in his or her own right in a self only or self and family enrollment even though his or her spouse also has a self and family enrollment. To ensure that no person receives benefits under more than one enrollment, each enrollee must tell the insurance carrier which family members are covered under his or her enrollment. These individuals are not covered under the other enrollment.

* * * * *

5. In § 890.305, paragraph (b) is revised to read as follows:

§ 890.305 Reinstatement of enrollment after military service.

* * * * *

(b) An employee whose employing office terminates his or her enrollment because his or her order to enter on duty in a uniformed service is for a period longer than 30 days, and who retires on an immediate annuity from his or her Federal civilian position while on such duty, may reinstate his or her enrollment by asking to do so within 60 days after retirement. In the absence of such a request, the retirement system automatically reinstates the enrollment on the day the person separates from the uniformed service. For the retirement system to reinstate the enrollment, the individual must have been covered under this part since his or her first opportunity or for the 5 years of civilian service (excluding the period of uniformed service) immediately preceding the civilian retirement, whichever is shorter.

6. Section 890.307 is revised to read as follows:

§ 890.307 Waiver or suspension of annuity or compensation.

(a) Except as provided in paragraphs (b) and (f) of this section, when annuity or compensation is entirely waived or suspended, the annuitant's enrollment continues for not more than 3 months (not more than 12 weeks for annuitants whose compensation under subchapter I of chapter 81 of title 5, United States Code, is paid each 4 weeks). If the waiver or suspension continues beyond this period, the employing office will notify the annuitant in writing that the employing office will terminate the enrollment effective at the end of the period, subject to the temporary extension of coverage for conversion, unless the annuitant elects to make payment of the premium directly to the employing office during the period of waiver. If the annuitant elects to have the enrollment terminated, the employing office automatically reinstates the enrollment on a prospective basis when the annuitant again receives payment of annuity or compensation. The employing office will make the withholding for the period of waiver or suspension during which enrollment was continued (i.e., 3 months or less).

(b) If the annuitant elects to pay premiums directly, he or she must send to the employing office his or her share of the subscription charge for the enrollment for every pay period during which the enrollment continues, exclusive of the 31-day temporary extension of coverage for conversion provided in § 890.401. The annuitant must pay after each pay period he or she is covered in accordance with a schedule established by the employing office. If the employing office does not receive payment by the date due, the employing office will notify the annuitant by certified mail return receipt requested that coverage will continue only if payment is made within 15 days after receipt of the notice. The employing office will terminate the enrollment of an annuitant who fails to pay within the specified time frame. The employing office will automatically reinstate the enrollment on a prospective basis when payment of annuity or compensation resumes.

(c) If the annuitant is prevented by circumstances beyond his or her control from paying within 15 days after receipt of the notice, he or she may request reinstatement of coverage by writing to the employing office. The annuitant must file the request within 30 calendar days from the date of termination, and must include supporting documentation. The employing office

will determine if the annuitant is eligible for reinstatement of coverage; and, when the determination is affirmative, reinstate the coverage of the annuitant retroactive to the date of termination. If the determination is negative, the annuitant may request a review of the decision as provided in § 890.104.

(d) Termination of enrollment for failure to pay premiums within the time frame established in accordance with paragraph (b) of this section is retroactive to the end of the last pay period for which the employing office timely received payment.

(e) The employing office will submit all direct premium payments along with its regular health benefits premiums to OPM in accordance with procedures established by OPM.

(f) If suspension of annuity or compensation is because of reemployment, the reemploying office must make the withholding currently and enrollment continues during reemployment.

§ 890.701 [Amended]

7. Section 890.701 is amended by removing the last sentence of the definition of *Medically underserved area.*

§ 890.808 [Amended]

8. In § 890.808, paragraph (a) is amended by removing "§ 890.805(d)" and adding in its place "§ 890.805(b)" and by removing "§ 890.805(e)" and adding in its place "§ 890.805(c)".

[FR Doc. 94–28929 Filed 11–22–94; 8:45 am]
BILLING CODE 6325–01–M

DEPARTMENT OF AGRICULTURE

Farm Service Agency

7 CFR Chapter VII and Part 703

RIN 0560–AD59

Wetlands Reserve Program

AGENCY: Farm Service Agency, USDA.

ACTION: Final rule.

SUMMARY: Title XII, section 1237 of the Food Security Act of 1985 (1985 Act), as amended, was amended by the Omnibus Budget Reconciliation Act of 1993 to specify the number of acres the Secretary of Agriculture shall enroll in the Wetlands Reserve Program (WRP). This final rule: adopts, with changes, the interim rule published in the **Federal Register** on January 27, 1994; makes other minor modifications for clarity and ease of administration, and; revises the policy regarding the eligibility of certain land for enrollment in the WRP. In addition, this rule amends 7 CFR Chapter VII to reflect the abolishment of ASCS and the establishment of the Farm Service Agency in the recent Department of Agriculture reorganization.

EFFECTIVE DATE: November 23, 1994.

FOR FURTHER INFORMATION CONTACT: James R. McMullen, Farm Service Agency, P.O. Box 2415, room 4714–S, Washington, DC 20013–2415; telephone 202–720–6221.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This final rule was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866. It has been determined significant because of the need for interagency coordination.

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable to this rule because FSA is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

Environmental Evaluation

It has been determined by an environmental evaluation that this action will not have any significant adverse impact on the quality of the human environment. Therefore, neither an environmental impact statement nor environmental assessment is needed. Copies of a final environmental evaluation are available upon request.

Executive Order 12372

This program/activity is not subject to the provisions of Executive Order 12372 because it involves direct payments to individuals and not to State and local officials. See notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

Federal Domestic Assistance Program

The title and number of the Federal Domestic Assistance Program, as found in the Catalog of Federal Domestic Assistance, to which this rule applies are: Wetlands Reserve Program—10.072.

Paperwork Reduction Act

The information collection requirements of this final rule at 7 CFR part 703 have been approved through January 31, 1997, by OMB under provisions of 44 U.S.C. 33. The public reporting burden for the information collections that would be required for compliance with these regulations is estimated to average 39 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Executive Order 12778

This final rule has been reviewed in accordance with Executive Order 12778. The provisions of this final rule are not retroactive and preempt State and local laws to the extent such laws are inconsistent with the provisions of this final rule. Before an action may be brought in a Federal court of competent jurisdiction, the administrative appeal rights afforded program participants at 7 CFR part 780 must be exhausted.

Discussion of Program

The current regulations in 7 CFR part 703, published as an interim rule on January 27, 1994 (59 FR 3772), implemented the 1994 WRP, which is authorized by Title XII of the 1985 Act. Under the WRP, FSA will purchase easements, in lump-sum payments, from persons owning cropland who voluntarily agree to restore and protect farmed wetlands, prior converted croplands, substantially altered lands, and eligible adjacent land. Fund and acreage allocations will be provided to States based on landowner interest and other factors as determined by the Deputy Administrator, State and County Operations, FSA, in consultation with the Natural Resource Conservation Service and the Fish and Wildlife Service. Land eligible for enrollment in the WRP includes farmed wetlands, prior converted croplands, but not land converted after December 23, 1985, or substantially altered lands, together with adjacent lands on which the wetlands are functionally dependent so long as the likelihood of successful restoration of such land and the wetland values merit inclusion in the program taking into account the cost of restoring the wetlands and the cost of acquiring an easement. FSA is also permitted to include in the program:

(1) Farmed wetlands, prior converted croplands, substantially altered lands, and lands which are enrolled in the Conservation Reserve Program (CRP), as authorized by Title XII of the 1985 Act, with the highest wetland functions and values and that are likely to return to production at the end of the CRP contract;

(2) Other wetlands that would not otherwise be eligible if it is determined that inclusion in the program would add to the value of the easement; and

(3) Riparian areas that link wetlands which are protected by easements or by some other device or circumstance that achieves the same purpose as an easement.

Landowners are not eligible to receive funding under both the Emergency Conservation Program (ECP) and the WRP with respect to the same acreage. ECP payments received with respect to acreage offered for WRP must be refunded, provided the ECP practice is still within its lifespan provisions, before any WRP payment will be disbursed.

This final rule does not impact the Emergency Wetlands Reserve Program as authorized by the Emergency Supplemental Appropriations for Relief From the Major, Widespread Flooding in the Midwest Act of 1993 (Pub. L. 103–75).

Discussion of Comments

FSA received 4 letters containing 23 comments concerning the interim rule published January 27, 1994. Entities responding included national wildlife and conservation organizations and one State farm organization.

Changes in this final rule from the interim rule of January 27, 1994, are minor. Changes have been made for clarity, editorial purposes, and to facilitate the application of the regulations. In addition, reference has been added to the provisions in § 703.6 with respect to the eligibility of foreign persons to participate in the WRP and provisions for eligible land have been revised in § 703.7.

A comment was received from one respondent who recommended that FSA use a more open process than what was used during the first WRP signup period. Specifically, ranking factors and weights and any State level modifications should be available and understandable. FSA had already adopted this policy, effective for the second signup period.

Another respondent recommended that FSA mount a campaign to educate landowners about WRP. FSA has made significant efforts to educate landowners about WRP through formal public meetings, informal question and answer sessions, and other information activities, such as, press releases. Meetings were held with nongovernment organizations, including farm and commodity groups, conservation and environmental organizations, attorneys, lenders, and appraisers, where the organizations were encouraged to distribute information to their constituents.

One respondent was pleased to see more explicit environmental criteria in the rule and more discretion given to State level Federal officials and resource professionals.

Another respondent recommended that the Federal government help pay for the maintenance of the acreage enrolled in WRP. Neither the 1985 Act nor the laws governing real estate acquisition by the Federal government provide authority to adopt this recommendation. Landowners will be fully informed by FSA personnel of maintenance requirements prior to filing the easement and the landowner may withdraw from the WRP, without the assessment of any penalty, at any time prior to the filing of the WRP easement.

Several comments were received regarding the appraisal process. Respondents generally accepted the appraisal process. However, one respondent was concerned about the logistics of obtaining and paying for appraisals for all applicants. FSA will not appraise all sites on which an intention was submitted. Appraisals will be performed only on sites that are tentatively selected through the evaluation process and have been agreed to by the landowner.

Another respondent believes that local governments will lose a source of revenue as property in WRP may be devalued. The respondent recommends the Federal government supplement local governments with the tax money that is lost. FSA has no authority to implement this recommendation. It should also be noted that in a number of cases, land enrolled in the WRP yields an increased land value.

One respondent inquired about landowners requirements with capital gains tax on land entered into the WRP. FSA has no responsibilities regarding this and other tax issues. Landowners are advised to seek assistance from their attorney or State and Federal tax officials.

The discussion that follows is organized in the same sequence as the final rule.

Section 703.3—Definitions

For clarity, a definition for "restoration" has been added to read "restoration means the restoration of both the hydrology and native vegetation that occurred on the site prior to the conversion of a wetland.

Section 703.7—Eligible land

One respondent commented that easements should be accepted on lands where existing hydrologic conditions exist for wetlands to be restored or where such hydrologic conditions will be restored. FSA has previously adopted this provision.

Another commented that § 703.7(a)(1)(ii) needed to include the phrase "and cost of acquiring the easement" at the end of the sentence to be consistent with § 703.2(f)(1). FSA agreed and has amended this section accordingly.

Section 703.9—Transfer of lands from the CRP to the WRP

One respondent suggested the rule be modified to allow Water Bank Program (WBP) lands to be enrolled in the WRP similar to the process used for CRP. FSA does not have the authority to implement this recommendation. The 1985 Act includes references to land enrolled in the CRP, but not WBP acreage, as "other eligible land."

Section 703.12—Obligations of the Landowner

Three respondents commented on the easement length. One recommended FSA modify the rule to allow the use of 30-year easements in States where permanent easements are prohibited; another recommended the duration of the easements should remain perpetual but allow for landowners to buy back land after 30 years if the purpose of the easement no longer exists; and the third recommended allowing farmers to choose between perpetual and long-term easements. Interest in WRP with permanent easements far exceeds the appropriation levels for the program; therefore, FSA will continue to give priority to permanent easements.

One respondent commented in support of the easement filing deadline. However, FSA may need some flexibility to adjust the deadline period. FSA believes 12 months from the end of signup is adequate time to have all the appropriate administrative work completed for filing an easement. In exceptional cases, the regulation allows the Deputy Administrator, FSA, to authorize additional time for completion of the enrollment process.

Another respondent recommended FSA convert from a reserve interest deed to a "hybrid" type of easement used by private nonprofit organizations which spells out specific land use restrictions as well as a general prohibition on incompatible uses and relies on continuous monitoring by accountable local partners to assure compliance. The respondent believes this approach results in the enrollment of higher-quality wetlands by appealing to more landowners and it would yield greater conservation benefits than the current FSA approach. The respondent is skeptical of the "top-down law enforcement" approach to easement compliance.

Substantial environmental benefits have been secured through the filing of permanent easements since fiscal year 1992 and interest has far exceeded enrollment authorities. FSA believes that the greater environmental benefits, if any, as proposed by the respondent will be minimal while significant losses in assurances that the acreage will be maintained will be suffered. Therefore, FSA did not adopt the recommendation.

Another respondent commented that the drainage on acreage surrounding the WRP site should not be impeded. FSA has been assured by the technical agencies that plans will be developed with landowners to ensure the landowners conservation objectives are met while ensuring that no acreage will be enrolled that is not a viable wetland.

Another respondent agreed with the provision that allows landowners to limit public access to the WRP site.

Section 703.13—Payments to Landowners by FSA

One respondent commented that USDA administrative guidelines should make clear that the cost of land appraisals required by this rule will be paid with Federal funds even when a landowner eventually decides not to enroll in WRP. FSA has previously implemented this procedure.

Section 703.15—Wetlands Reserve Plan of Operations

Respondents were generally in favor of the provisions in this section. However, one respondent inquired whether landowners would be able to sell mineral rights on acreage enrolled in WRP. FSA has determined that, providing the extraction of the minerals associated with the sale of the mineral rights is compatible with the wetland functions and values, landowners may continue to utilize the rights in the normal manner. However, if the rights are incompatible with the wetland site, the site would not be accepted into the program.

Section 703.25—Appeals

One respondent thought that withholding appraisals and supporting documentation from the public was inappropriate. FSA added this provision to conform with guidelines established in 49 CFR part 24, Uniform Relocation Assistance and Real Property Acquisition for Federal and Federally Assisted Programs. Accordingly, no change has been made to this regulation.

Establishment of the Farm Service Agency

Pursuant to Public Law 103–354, the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, the Secretary of Agriculture issued Secretary's Memorandum 1010–1, Reorganization of the Department of Agriculture, on October 20, 1994. That memorandum orders the abolishment of the Agricultural Stabilization and Conservation Service and the establishment of the Farm Service Agency, which assumes the functions previously performed by the Agricultural Stabilization and Conservation Service. This rule includes amendments to 7 CFR chapter VII which are necessary to bring agency regulations into alignment with the departmental reorganization.

List of Subjects in 7 CFR Part 703

Administrative practices and procedures, Appraisals, Compliance procedures, Easements, Natural resources, Technical assistance and Wetlands Reserve Plan of Operations (WRPO).

Accordingly 7 CFR Chapter VII and part 703 are amended as follows:

1. The heading of 7 CFR chapter VII is revised to read as follows:

CHAPTER VII—FARM SERVICE AGENCY, DEPARTMENT OF AGRICULTURE

2. In 7 CFR chapter VII, all references to "Agricultural Stabilization and Conservation Service" are revised to read "Farm Service Agency", and all references to "ASCS" are revised to read "FSA".

3. The interim rule published on January 27, 1994 (59 FR 3772), is adopted as final with the following changes set forth below, and part 703 is further amended as follows:

PART 703—WETLANDS RESERVE PROGRAM

A. The authority citation for 7 CFR part 703 continues to read as follows:

Authority: 16 U.S.C. 3837 *et seq.*

§ 703.1 [Amended]

B. In § 703.1, the introductory paragraph (a) is amended by removing the words "shall be" in the second sentence and inserting the word "was" in their place, and paragraph (b) is amended by adding "riparian areas," after "prior converted croplands," in the first sentence.

C. Section 703.3 (b) is amended by adding the definition of "Restoration" to read as follows:

§ 703.3 Definitions.

* * * * *

(b) * * *

* * * * *

Restoration means the restoration of both the hydrology and native vegetation that occurred on the site prior to conversion to a wetland.

* * * * *

D. Section 703.6 is revised to read as follows:

§ 703.6 Eligible person.

To be eligible to offer land for the WRP, a person must:

(a) Be a U.S. citizen or otherwise meet the provisions in 7 CFR part 1498;

(b) Be the owner of the eligible property for which enrollment is sought;

(c) Have been the owner of such land for at least the preceding 12 months prior to the end of the period in which the intent to participate is declared, as provided in this part, unless:

(1) It is determined by FSA that the land was acquired by will or succession as a result of the death of the previous owner; or

(2) It is determined by FSA that adequate assurances have been presented that the new owner of such land did not acquire such land for the purpose of placing it in the WRP.

5. Section 703.7 is amended by revising paragraphs (a)(1)(i), (a)(2)(i) and (d)(2) as follows:

§ 703.7 Eligible land.

(a)(1) * * *

(i) Is wetland farmed under natural conditions, a farmed wetland, prior converted cropland except that converted lands shall not be eligible for enrollment if the conversion was not commenced prior to December 23, 1985, substantially altered lands, or any former wetland intensively managed for a food or forage crop; and

(ii) Merits inclusion in the program based on the likelihood of successful restoration of the enrolled land and the resultant wetland values when considering restoration cost and the cost of acquiring the easement.

(2) * * *

(i) Have been annually planted or considered planted to an agricultural commodity or have produced any other crop intensively managed for food or forage as approved by the Deputy Administrator in at least 1 of the 5 crop years 1986 through 1990, and have been capable of being cropped in 1992 or 1993;

* * * * *

(d) * * *

(2) Land adjacent to the restored wetland, which would contribute significantly to the restoration of adjacent wetlands, but not more than 25 percent of the total easement area as needed to protect the functions and values of wetlands restored under this

part, unless the Deputy Administrator determines a larger area is necessary to meet the objectives of the WRP. These areas are limited to buffer areas, inclusions, and noncropped natural wetlands;

* * * * *

§ 703.8 [Amended]

6. Section 703.8(b) is amended by removing the words "timber stands or".

§ 703.13 [Amended]

7. In § 703.13, the introductory text of paragraph (a) is amended by adding the words "after an easement is filed" at the end of the first sentence.

§ 703.16 [Amended]

8. Section 703.16 is amended by adding the words "as previously determined by the technical agency" at the end of the paragraph.

Signed at Washington, DC, on November 10, 1994.

R.E. Rominger,

Acting Administrator, Farm Service Agency and Deputy Secretary, United States Department of Agriculture.

[FR Doc. 94–28598 Filed 11–22–94; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Parts 550, 552, 562, 563 and 571

[No. 94–246]

RIN 1550–AA68

Annual Independent Audits

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Final rule.

SUMMARY: The Office of Thrift Supervision (OTS) is adopting a final rule that amends its annual independent audit requirements for savings associations to be more consistent with those applicable to other federally insured depository institutions. Pursuant to Section 112 of the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA) all insured depository institutions with total assets of $500 million or more are required to obtain an annual independent audit. OTS is amending its rules in order to eliminate the mandatory annual independent audit requirement for small savings associations with composite CAMEL ratings of 1 or 2; to rely on the FDICIA section 112 independent audit requirements for savings associations with assets of $500 million or more; and to adopt regulatory language to allow OTS to require an independent audit of any savings association with assets of less than $500 million, as needed for purposes of safety and soundness.

EFFECTIVE DATE: December 23, 1994.

FOR FURTHER INFORMATION CONTACT: David H. Martens, Chief Accountant, (202) 906–5645, Timothy J. Stier, Deputy Chief Accountant, (202) 906–5699, Office of Thrift Supervision, 1700 G Street, NW., Washington, D.C. 20552.

SUPPLEMENTARY INFORMATION:

I. Background and Description of Proposal

On March 22, 1994, OTS published a notice of proposed rulemaking to amend the regulatory framework governing independent audits of savings associations' financial statements. The proposed amendments were designed to achieve comparability with the framework used by the other Federal banking agencies [1] for banks. Historically, OTS regulations and policies required all savings associations and savings and loan holding companies to obtain an annual independent audit of their financial statements. In contrast, the regulations and policies of the other Federal banking agencies generally encourage all banks and bank holding companies to obtain an annual independent audit, but only mandate that certain institutions obtain audits. OTS' proposal recognized that a well planned and executed independent audit could improve the reliability of regulatory reports, such as the Thrift Financial Report (TFR). The proposal also recognized, however, that the current OTS audit requirement could be modified to reduce regulatory burden without increasing the risk of unsafe and unsound regulatory reporting.

Under the proposal, savings associations with assets of $500 million or more would continue to be audited pursuant to Section 112 of FDICIA [2] and the FDIC's implementing regulation 12 CFR Part 363. The FDIC regulation requires audits of all FDIC-insured depository institutions with assets of $500 million or more, includes financial statement and internal control reporting requirements, and sets minimum qualifications for independent public accountants and for members of the board of directors' audit committee.

Under the proposal, small savings associations (*i.e.*, those with assets of less than $500 million), were required to obtain annual independent audits of their financial statements whenever OTS believed an independent audit was necessary to supplement other safety and soundness supervisory activities. The proposal included a request for comment on the specific safety and soundness criteria that should be used to determine when such an audit would be appropriate. The proposal required that such audits utilize the same qualifications for independent public accountants as those applicable to institutions covered by the FDIC regulation. The proposal provided that when small savings associations obtained an audit voluntarily the audit would be conducted in accordance with generally accepted auditing standards (GAAS) and the resulting reports and supporting audit work papers would be made available to OTS upon request.

Finally, the proposal included specific requests for comment on the audit requirements for trust operations, holding company financial statements, and savings associations overall. The objective of these inquiries was to assist OTS in developing an audit approach for these types of audits that would be responsive to the safety and soundness needs and comparable to the approach used by the other Federal banking agencies.

II. Summary of Comments and OTS Response

OTS received ten comment letters on the proposal. Commenters included seven savings associations, two trade associations, and a Federal banking agency. Overall, the commenters were supportive of the proposal and offered suggestions on implementing the approach. Only one commenter (a thrift) expressed significant opposition to the elimination of the mandatory audit requirement. Commenters also responded to the six specific requests for comment that were included in the proposal. The issues and comments raised by those responses are addressed below.

A. Benefits of Annual Independent Audits to Small Savings Associations

Five small savings associations commented on the issue of whether audits were beneficial to small savings associations and improved the accuracy of the Thrift Financial Report (TFR). Four of the commenters suggested that audits were of little or no benefit since

[1] The term "other Federal banking agencies" means the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, and the Federal Deposit Insurance Corporation.

[2] This provision is codified at section 36 of the Federal Deposit Insurance Act ("FDI Act"), 12 U.S.C. 1831m.

they typically do not focus on the association's internal operations or the TFR process. In addition, these commenters suggested that audits often overlapped with OTS safety and soundness examinations in key areas. One commenter suggested that audits were quite valuable because they are often the only independent review of management's activities.

OTS believes that an independent audit can help address safety and soundness concerns regarding the accuracy of an institution's financial reports and the effectiveness of its internal controls over financial reporting. Nonetheless, OTS believes that decision should be left to the management of healthy savings associations that meet the size and composite rating criteria discussed above.

Therefore, the final rule eliminates the mandatory annual audit requirement for institutions with less than $500 million in assets and composite CAMEL ratings of 1 or 2. The rule is intended to reduce the regulatory burden on those institutions while ensuring consistency between the audit requirements administered by the OTS and those administered by the FDIC. It is *not* intended to discourage such an institution from obtaining an annual independent audit. Management should carefully consider the value of the annual independent audit to the safety, soundness, and effectiveness of the institution's control systems in deciding whether to continue the practice.

OTS will retain its ability to require audits of any small savings associations that present certain safety and soundness concerns as discussed in Item B below.

B. Safety and Soundness Concerns

Most of the commenters suggested alternatives to the mandatory audit requirement that would mitigate the risk of unsafe and unsound regulatory reporting. Three commenters suggested that independent audits be required for all MACRO (CAMEL) 4 or 5 rated institutions or other supervisory measures of risk. These commenters also suggested that a waiver provision be included in any safety and soundness requirement. Two commenters suggested that OTS simply rely on the judgment of institution boards of directors to determine whether an audit is needed and specifically encourage boards of directors to obtain audits as part of a plan for sound financial reporting.

OTS has decided to use the CAMEL 3, 4 and 5 rating as a measure of risk to identify when an independent audit is required. An institution that receives a CAMEL 3 rating for safety and soundness concerns exhibits a combination of financial, operational, or compliance weaknesses. When weaknesses relate to financial condition, such institutions may be vulnerable to the onset of adverse business conditions and could easily deteriorate if concerted action is not effective in correcting the areas of weakness. An institution that receives a CAMEL 4 or 5 rating has a significant level of serious financial weaknesses or a combination of other conditions that are unsatisfactory. For these reasons, OTS believes that an audit requirement for CAMEL 3, 4 or 5 rated institutions is generally an effective use of independent audit resources. The rule thus requires a CAMEL 3, 4 or 5 rated institution to obtain an independent audit, unless notified otherwise by OTS.

OTS recognizes that an institution may receive a CAMEL 3, 4 or 5 rating for safety and soundness concerns unrelated to any issue that would be addressed by an independent audit. It also recognizes that the FDIC Board chose not to require independent audits of all troubled banks. As a result, the final rule provides that in certain cases, the OTS Director may determine that the independent audit is unnecessary, and the required audit would be waived for the institution in question. In addition, the OTS Director may modify the audit requirement by requiring procedures agreed to by OTS if such agreed upon procedures are effective to address specific safety and soundness concerns that a particular institution presents.

The Director's authority to require audits on a case-by-case basis, or to waive or modify an audit requirement in appropriate circumstances may be delegated.

C. OTS Access to Work Papers of Small Savings Association Audits

Five commenters responded to the issue of whether OTS should have access to audit work papers in cases where a small savings association obtains an audit voluntarily. Most of the commenters were in favor of granting access to work papers if it increases the efficiency of the examination process. Two commenters were opposed to granting access to audit work papers based on the rationale that by rescinding the audit requirement, OTS is no longer an intended beneficiary of the audit process.

In the interest of eliminating duplicative efforts, OTS believes it would be beneficial for small savings associations, who voluntarily have audits, to have their independent auditors make audit work papers available to OTS as part of their audit engagement. OTS encourages candid communication between examiners and independent auditors. OTS policy encourages examiners to utilize independent audit work papers to plan examinations and to reduce duplicative efforts and to share examination work products with independent auditors. OTS believes that it would be extremely beneficial for examiners and auditors to continue to share their work products. Therefore, OTS will require that the engagement letters for required and voluntary audits contain a provision that gives OTS access to the audit work papers. This provision is a continuation of the current OTS policy in Public Accountant (PA) Bulletin 7a, "Audits of Insured Institutions, Service Corporations and Joint Ventures by Independent Public Accountants."

D. Holding Company Audit Requirements

A few commenters presented suggestions on the manner in which OTS should determine whether a savings and loan holding company is required to obtain an audit for safety and soundness purposes. One commenter suggested OTS utilize the same requirements that are applicable to bank holding companies. Currently, the rules and policies applicable to bank holding companies require an annual independent audit of all holding companies with consolidated assets of $150 million or more. Other commenters suggested that savings and loan holding companies be required to obtain an audit if they are a multiple holding company (*i.e.*, owner of more than one depository institution) or have assets in excess of $1 billion.

An objective in developing the overall OTS audit approach was to attain comparability with the other Federal banking agencies. Because the Federal Reserve's bank holding company audit requirement and the FDIC's insured depository institution audit requirement differ, OTS weighed the advantages and disadvantages of each agency's asset threshold. Setting a lower asset threshold (*i.e.*, $150 million) at the holding company level would, in effect, require certain insured subsidiary institutions to obtain an audit that would otherwise not have been required by the FDIC.

In determining the exposure to a thrift posed by its parent holding company, the OTS focuses primarily on the relationship and transactions between the thrift and its affiliates. OTS believes that its current holding company

regulatory structure limits the risks from intercompany transactions that may not be in the best interests of the thrift.

To avoid situations where the holding company audit requirement would essentially create an audit requirement for the subsidiary institution, OTS has decided against adopting the Federal Reserve's $150 million threshold for bank holding companies. Instead, OTS will require audits of holding companies whose subsidiary savings association(s) have aggregate assets of $500 million or more. OTS selected the $500 million asset threshold to achieve comparability with the approach utilized in the FDIC regulation. This requirement has also been incorporated into the instructions to the annual/current holding company report H–(b)11.

The final rule provides that the Director of OTS may require, at any time, an independent audit of any savings and loan holding company, with aggregate assets of less than $500 million, when needed for purposes of safety and soundness.

E. Alternatives to Auditing Procedures for Bank Secrecy Act and Third Party Reviews of Service Bureaus That Could Be Used To Address Safety and Soundness Concerns

A few commenters responded to the issue of whether OTS should continue to have independent auditors perform procedures to test compliance with the Bank Secrecy Act (BSA) and apply OTS standards for third-party reviews of service bureau internal controls. Commenters indicated that BSA compliance and service bureau internal controls should be tested in more detail by an institution's internal audit staff and OTS examiners.

OTS initially required independent auditors to test savings associations' compliance with the BSA as part of a strategy to closely monitor currency transactions. Since that time, OTS has expanded the scope of examination procedures in this area and required their application in all types of examinations. OTS believes that BSA compliance is now adequately tested through the internal audit functions of institutions and the examination process. In December of 1993, OTS rescinded PA Bulletin 7a–3, "Auditors' and Accountants' Responsibilities Under Currency and Foreign Transactions Reporting Act (Bank Secrecy Act)". No audit requirements for testing compliance with the BSA are included in the final rule.

OTS issued its standards for third party reviews of service bureaus at a time when there was limited supervisory and professional auditing guidance on the subject. Since that time, OTS and the other banking agencies have developed a uniform examination approach for EDP functions including service bureaus. The auditing profession has also revised its standards on several occasions to address testing of service bureau internal controls. In addition, under the proposed OTS Standards for Safety and Soundness regulations, promulgated pursuant to section 39 of the FDI Act, associations would be required to maintain an internal audit system that adequately tests and reviews internal controls and information systems, including service bureaus. OTS believes that service bureau internal controls are adequately tested through an institution's internal audit function and the OTS examination process. Therefore, PA Bulletin 7–1a, "Standards for Audits of Insured Institutions Using Electronic Data Processing" will be rescinded.

F. Trust Audits

Several commenters presented suggestions on the requirements for audits of savings association trust departments. Two commenters suggested that trust departments should be audited based on the volume or dollar value of trust assets managed. Commenters indicated that trust department audits could be performed by internal auditors, external auditors, or OTS examiners. Commenters also suggested that trust department audits were generally more beneficial to the institution when performed by the internal audit function or as part of an OTS compliance review.

OTS believes that the approach for trust audits outlined in the proposal combined with examination procedures is responsive to safety and soundness concerns. Therefore, the final rule will implement the approach outlined in the proposal.

III. Description of Final Rule

A. General

The final rule generally follows the approach outlined in the proposal. Savings associations and savings and loan holding companies are no longer required to have independent audits except in cases where: (1) FDIC rule 12 CFR Part 363 requires independent audits of savings associations; (2) OTS requires independent audits of savings and loan holding companies (*i.e.*, holding companies with aggregate insured depository assets of $500 million or more); or, (3) OTS requires an independent audit, or agreed-upon procedures, of a savings association or savings and loan holding company due to safety and soundness concerns (*e.g.*, CAMEL 3, 4 or 5 examination rating for savings associations or other identified safety and soundness concerns).

The final rule also includes two technical corrections to 12 CFR 562.3—Statements of Condition—that were not included in the proposal. First, the final rule amends 12 CFR 562.3(b)(2) to eliminate language requiring savings associations to make their audited financial statements available to depositors upon request. This change was necessary due to the fact that the final rule eliminates the mandatory audit requirement. Any member of the public may obtain a copy of the audited financial statements of a savings association, or other FDIC-insured depository institution, that files a report with the FDIC pursuant to FDIC rule 12 CFR Part 363 simply by making a request to the institution.

Second, the final rule amends 12 CFR 562.3(d) to eliminate a cross reference to 12 CFR 571.2. This change was necessary due to the fact that the final rule eliminates 12 CFR 571.2.

B. Securities Filings

The final rule does not affect any of the auditing standards, accounting standards, or other requirements for financial statements contained in securities filings submitted to OTS pursuant to the Securities Exchange Act of 1934 (1934 Act) or OTS regulations parts 563b, 563d, or 563g (Securities filings). Applicable federal securities laws and regulations require securities filings to comply with generally accepted accounting principles (GAAP) and to include financial statements and other information that have been audited by independent public accountants in accordance with GAAS. Savings associations anticipating a conversion from mutual to stock form of ownership, or any other transaction governed by the federal securities laws and regulations, should note that the accounting or auditing requirements for such securities filings continue to apply.

IV. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, it is certified that this rule will not have a significant economic impact on a substantial number of small entities. The rule is expected to relieve a regulatory burden on savings associations with assets of less than $500 million. The overall economic impact is not expected to be significant because it is anticipated that many of these institutions will continue on a voluntary basis to obtain annual independent audits. Therefore,

Regulatory Flexibility Act analysis is not required.

V. Paperwork Reduction Act

The reporting requirements contained in this final rule have been submitted to and approved by the Office of Management and Budget under OMB Control No. 1550–0082 for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collections of information should be sent to the Office of Management and Budget, Paperwork Reduction Project (1550), Washington, DC 20503 with copies to the Office of Thrift Supervision, 1700 G Street NW., Washington, DC 20552.

The reporting requirements in this proposal are found in 12 CFR 550.7(a) and 12 CFR 562.4(a). The information is needed by OTS to provide an orderly mechanism for expeditiously processing requests for non-public information while ensuring confidentiality. The likely recordkeepers are Federal savings associations.

VI. Executive Order 12866

OTS has determined that this final rule does not constitute a "significant regulatory action" for purposes of Executive Order 12866.

VII. Effective Date

OTS has provided for a 30-day delayed effective date for this rule. *See* 5 U.S.C. 553(d). The Riegle Community Development and Regulatory Improvement (CDRI) Act of 1994, which was signed by the President on September 23, 1994, imposes further effective date requirements with respect to regulations issued by the Federal banking agencies. Section 302(b) of that law requires the agencies to delay the effective date of new regulations that "impose additional reporting, disclosures, or other new requirements on insured depository institutions" until the first day of the first calendar quarter after the regulations are published in final form. An exception to this requirement is available if the agency determines, "for good cause published with the regulation," that the regulation should become effective sooner.

Although the principal effect of today's rule is to relieve restrictions rather than to impose "new requirements" on insured depository institutions, certain of its provisions arguably fall within the scope of coverage of the CDRI Act's effective date provision. For the following reasons, however, the OTS has concluded that good cause exists to accelerate the effective date that would be required by the CDRI Act.

Application of this CDRI Act effective date provision would cause today's rule to take effect on January 1, 1995. OTS's current rules require all savings associations to be audited at least once in each calendar year. If the effective date of today's rule is delayed until January 1, 1995, then it will not exempt any savings associations from their obligation to obtain an audit in calendar year 1994. The result would be to require those associations that are relieved of the annual audit requirement under today's rule to incur the burden and expense of an annual independent audit for no reason other than the timing imposed by the CDRI Act's delayed effective date provision. This result would be inconsistent with the purpose of section 302 of the CDRI Act, which is generally to reduce regulatory burden and the cost of compliance. *See* H.R. Conf. Rep. No. 103–652, 103d Cong., 2d Sess. 168 (1994). Accordingly, the OTS finds good cause for the rule to become effective earlier than the date that the CDRI Act would otherwise require.

Finally, the OTS notes that the CDRI Act effective date provision applies only to regulations affecting insured depository institutions. Regulations applicable to holding companies are therefore beyond the scope of the provision.

List of Subjects

12 CFR Part 550

Reporting and recordkeeping requirements, Savings associations, Trusts and trustees.

12 CFR Part 552

Reporting and recordkeeping requirements, Savings associations, Securities.

12 CFR Part 562

Accounting, Reporting and recordkeeping requirements.

12 CFR Part 563

Accounting, Advertising, Crime, Currency, Flood insurance, Investments, Reporting and recordkeeping requirements, Savings associations, Securities, Surety bonds.

12 CFR Part 571

Accounting, Conflicts of interest, Gold, Investments, Reporting and recordkeeping requirements, Savings associations.

Accordingly, OTS hereby amends subchapters C and D, chapter V, title 12, Code of Federal Regulations, as set forth below:

SUBCHAPTER C—REGULATIONS FOR FEDERAL SAVINGS ASSOCIATIONS

PART 550—TRUST POWERS OF FEDERAL SAVINGS ASSOCIATIONS

1. The authority citation for part 550 is revised to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1735f–7.

2. Section 550.7 is revised to read as follows:

§ 550.7 Audit of trust department.

(a) A committee of directors of the Federal savings association who are independent of its management shall make, or cause to be made, a suitable audit of the association's trust department annually. The audit shall, at a minimum, ascertain whether the department has internal control policies and procedures in place to provide reasonable assurance that:

(1) Fiduciary activities are administered in accordance with applicable laws and regulations, governing trust instruments, and sound fiduciary principles;

(2) Fiduciary assets are properly safeguarded; and

(3) Transactions are accurately recorded in the appropriate accounts in a timely manner.

(b) The audit shall be conducted in accordance with generally accepted standards for attestation engagements and any other standards established by the OTS. The audit may be conducted by internal auditors, external auditors or other qualified persons who are responsible only to the board of directors.

PART 552—INCORPORATION, ORGANIZATION, AND CONVERSION OF FEDERAL STOCK ASSOCIATIONS

3. The authority citation for part 552 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a.

§ 552.6–4 [Removed and Reserved]

4. Section 552.6–4 is removed and reserved.

SUBCHAPTER D—REGULATIONS APPLICABLE TO ALL SAVINGS ASSOCIATIONS

PART 562—REGULATORY REPORTING STANDARDS

5. The authority citation for part 562 continues to read as follows:

Authority: 12 U.S.C. 1463.

6. Section 562.3 is amended by removing paragraph (b)(2), redesignating paragraph (b)(3) as paragraph (b)(2), and

revising paragraph (d) to read as follows:

§ 562.3 Statements of condition.

* * * * *

(d) *Alternative annual statement of condition.* The requirement of paragraph (a)(2) of this section is satisfied when a savings association makes copies of its audited financial statements conspicuously available to the public in its home office and each of its branch locations.

* * * * *

7. Section 562.4 is added to read as follows:

§ 562.4 Audit of savings associations and savings association holding companies.

(a) *General.* The OTS may require, at any time, an independent audit of the financial statements of, or the application of procedures agreed upon by the OTS to a savings association, savings and loan holding company, or affiliate (as defined by 12 CFR 563.41(b)(1)) by qualified independent public accountants when needed for any safety and soundness reason identified by the Director.

(b) *Audits required for safety and soundness purposes.* The OTS requires an independent audit for safety and soundness purposes:

(1) If, as of its most recent report of examination, a savings association has received a composite rating of 3, 4 or 5 on the CAMEL financial institutions' rating scale; or

(2) If, as of the beginning of its fiscal year, a savings and loan holding company controls savings association subsidiary(ies) with aggregate consolidated assets of $500 million or more.

(c) *Procedures.* (1) When the OTS requires an independent audit because such an audit is needed for safety and soundness purposes, the Director shall determine whether the audit was conducted and filed in a manner satisfactory to the OTS.

(2) The Director may waive the independent audit requirement for a savings association that, as of its most recent report of examination, has received a CAMEL rating of 3, 4 or 5, if the Director determines that an audit would not address the safety and soundness issues that caused the examination rating.

(3) When the OTS requires the application of procedures agreed upon by the OTS for safety and soundness purposes, the Director shall identify the procedures to be performed. The Director shall also determine whether the agreed upon procedures were conducted and filed in a manner satisfactory to the OTS.

(d) *Qualifications for independent public accountants.* The audit shall be conducted by an independent public accountant who:

(1) Is registered or licensed to practice as a public accountant, and is in good standing, under the laws of the state or other political subdivision of the United States in which the savings association's or holding company's principal office is located;

(2) Agrees in the engagement letter to provide the OTS with access to and copies of any work papers, policies, and procedures relating to the services performed;

(3) Is in compliance with the American Institute of Certified Public Accountants' (AICPA) Code of Professional Conduct and meets the independence requirements and interpretations of the Securities and Exchange Commission and its staff; and

(4) Has received, or is enrolled in, a peer review program that meets guidelines acceptable to the OTS.

(e) *Voluntary audits.* When a savings association, savings and loan holding company, or affiliate (as defined by 12 CFR 563.41(b)(1)) obtains an independent audit voluntarily, it shall be performed only by an independent public accountant who satisfies the requirements of paragraphs (d)(1), (d)(2), and (d)(3) of this section.

PART 563—OPERATIONS

8. The authority citation for part 563 continues to read as follows:

Authority: 12 U.S.C. 375b, 1462, 1462a, 1463, 1464, 1467a, 1468, 1817, 1828, 3806; 42 U.S.C. 4106.

§ 563.170 [Amended]

9. Section 563.170 is amended by removing paragraph (a)(2) and the paragraph designation of (a)(1).

PART 571—STATEMENTS OF POLICY

10. The authority citation for part 571 continues to read as follows:

Authority: 5 U.S.C. 552, 559; 12 U.S.C. 1462a, 1463, 1464.

§ 571.2 [Removed and Reserved]

11. Section 571.2 is removed and reserved.

Dated: November 17, 1994.

Jonathan L. Fiechter,

Acting Director.

[FR Doc. 94–28878 Filed 11–22–94; 8:45 am]

BILLING CODE 6720–01–P

RESOLUTION TRUST CORPORATION

12 CFR Part 1640

RIN 3205–AA25

Marketing and Selling Real Property on an Individual Basis and Disposition of Real Estate-Related Assets

AGENCY: Resolution Trust Corporation.

ACTION: Final rule.

SUMMARY: The Resolution Trust Corporation (RTC) is adopting the interim rule, which was published at 59 FR 47790 on September 19, 1994, as a final rule without change. The rule provides policies and procedures, required under subsections (w) (2) and (3) of section 21A of the Federal Home Loan Bank Act, for the marketing of real estate owned (REO) assets on an individual basis and for the disposition of REO assets with a book value of more than $400,000 and non-performing real estate loans with a book value of more than $1 million.

EFFECTIVE DATE: December 23, 1994.

FOR FURTHER INFORMATION CONTACT: William I. Jones, Counsel, RTC Legal Division, (202) 736–3106; Anne P. Depenbrock, Senior Attorney, (202) 736–0198; Kymberly Copa, Senior Attorney, (202) 736–3087; Steve A. Galloway, Small Investor Program Contact, (202) 416–4210; James R. Wigand, Assistant Vice President, Department of Operations and Asset Management, (202) 416–7133; Henry W. Abbot, Senior Asset Specialist, (202) 416–7132; Joseph W. Schantz, Asset Specialist, (202) 416–7302.

SUPPLEMENTARY INFORMATION:

Regulatory Procedure

Section 3(a) of the Resolution Trust Corporation Completion Act, enacted on December 17, 1993, added subsections (w) (2) and (3) of section 21A of the Federal Home Loan Bank Act ("FHLBA") (12 U.S.C. 1441a(w) (2) and (3)). Subsection (w)(2) requires the RTC to market real property on an individual basis for at least 120 days before making the property available on a portfolio basis or in a multi-asset sales initiative. With respect to non-performing real estate loans with a book value of more than $1 million and real property with a book value of more than $400,000, subsection (w)(3) establishes several marketing procedures for the RTC.

On September 19, 1994, the RTC published at 59 FR 47790 an interim rule with request for comments promulgating 12 CFR part 1640, implementing subsections (w) (2) and (3) of section 21A of the FHLBA.

Comments

The RTC received written comments only from the Savings and Community Bankers of America ("SCBA"). SCBA endorsed the interim rule and suggested no changes to the rule. During the comment period, the staff of the Thrift Depositor Protection Oversight Board asked RTC staff for clarification of some of the provisions in the rule. RTC staff supplied the clarification.

Final Rule

The RTC is making no changes to the interim rule in the adoption of the final rule. The supplementary information accompanying the interim rule provides an explanation of 12 CFR part 1640 and the reasons for its adoption.

Administrative Procedure Act

The RTC is adopting this rule as a final rule. It will be effective 30 days after publication in the **Federal Register**.

Final Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act, 5 U.S.C. 601, et seq., the following regulatory flexibility analysis is provided:

1. A succinct statement of the need for, and the objective of, the rule. The objective of the rule is to implement section 21A(w) (2) and (3) of the FHLBA, which establishes certain requirements for the RTC in the marketing and selling of real estate and certain other real estate related assets. The rule is needed in order to implement the requirements of the cited statutes.

2. A summary of the issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments. The one public comment received by the RTC endorsed the regulation as drafted in the interim rule. No changes were made as a result of that comment.

3. A description of each of the significant alternatives to the rule consistent with the stated objectives of applicable statutes and designed to minimize any significant economic impact of the rule on small entities which was considered by the agency, and a statement of the reasons why each one of such alternatives was rejected. The rule has no significant impact on small entities, and therefore, no alternatives to the rule were identified or considered.

List of Subjects in 12 CFR Part 1640

Savings associations.

Accordingly, the interim rule adding 12 CFR part 1640 which was published at 59 FR 47793 on September 19, 1994, is adopted as a final rule without change.

By order of the Deputy and Acting Chief Executive Officer.

Dated at Washington, DC, this 18th day of November 1994.

Resolution Trust Corporation.

John M. Buckley, Jr.,

Secretary.

[FR Doc. 94–28936 Filed 11–22–94; 8:45 am]

BILLING CODE 6714–01–M

SMALL BUSINESS ADMINISTRATION

13 CFR Part 109

Prepayment of Certain Small Business Investment and Certified Development Company Debentures

AGENCY: Small Business Administration (SBA).

ACTION: Interim final rule with request for comments.

SUMMARY: On October 22, 1994, the President signed Public law 103–403, The Small Business Administration Reauthorization and Amendments Act of 1994. Title V of that Act, "Relief From Debenture Prepayment Penalties", authorizes the Small Business Administration (SBA) to provide for relief from prepayment penalties currently imposed on certain issuers of debentures under the Small Business Investment Act of 1958 (Act). This interim final rule, published in accordance with Public Law 103–403, implements this new program.

DATES: This rule becomes effective on November 23, 1994. Comments must be submitted on or before December 23, 1994.

ADDRESSES: Comments should be sent to Allan S. Mandel, Director, Office of Rural Affairs and Economic Development (ORA&ED), Small business Administration, 409 Third Street SW., Suite 8300, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Allan S. Mandel, (202) 205–6485.

The Program

SUPPLEMENTARY INFORMATION: Public Law 103–403, enacted October 22, 1994, authorizes SBA to utilize the $30 million appropriated in Pub. L. 103–317 to provide relief from prepayment penalties currently imposed on the issuers of debentures which have been guaranteed by SBA and purchased by the Federal Financing Bank, an arm of the Treasury. Under these regulations, the issuer of a debenture which has been guaranteed by SBA and purchased by the Federal Financing Bank may, with the approval of SBA, prepay the debenture and penalty. Such prepayment may occur at the election of the borrower of a loan made with the proceeds of a debenture guaranteed under section 503 of the Act, or the issuer of a small business investment company debenture. A small business investment company operating under the authority of section 301(d) of the Act that has issued a debenture that was purchased by and is held by SBA may, under the same terms and conditions, prepay such debenture and penalty. It is anticipated that prepayment consistent with these regulations will result in reduced penalty payments for the issuers of the debentures and the borrowers of loans funded with their proceeds.

How the Program Will Work

Since 1958, SBA has operated a Small Business Investment Company (SBIC) program under which it guarantees the debentures of issuing small business investment companies operating under section 301(c) of the Act which are limited to investing in small businesses, or small business investment companies operating under authority of section 301(d) of the Act which are limited to investing in small businesses owned and controlled by socially or economically disadvantaged individuals (SBIC's and SSBIC's). Almost all of these debentures have terms of ten years or less. Prior to 1986, these debentures were guaranteed by SBA and sold to the Federal Financing Bank. The proceeds of those sales were remitted to the issuing investment companies which then invested them in the requisite small businesses. Since 1986, the Act has authorized debentures issued by both types of investment companies to be guaranteed by SBA and then pooled and sold to underwriters. Certificates backed by the pools are sold in the marketplace at market rates, and the proceeds of those sales are remitted to the issuing investment companies so that they may be used for investing in small businesses.

The SBIC issued debentures which will be affected by this program are those which will mature by April 1996. Debentures maturing thereafter are ones which have been pooled and sold in the capital markets and which are not subject to the prepayment provisions contemplated by the program. SSBIC issued debentures which will be affected are those which were issued since 1990, and which may be prepaid

through the issuance of another debenture or by the proceeds of the sale of preferred stock of the issuer which will be sold to SBA. Subsequently maturing debentures of companies are ones which have been pooled and sold in the private capital markets, and are not contemplated by the provisions of the program.

Because of the short remaining terms on the SBIC and SSBIC debentures which are eligible for the program, it is unlikely that any SBICs or SSBICs will benefit from the new prepayment provisions. Rather, it would be less expensive for the issuer directly to prepay the Federal Financing Bank in the case of SBIC issuers, or SBA in the case of SSBIC issuers. Nevertheless, all SBICs and SSBICs which are by definition eligible for the prepayment program, will be given the opportunity to make this determination themselves.

SBA has operated a Development Company Program which involves the guaranteeing of Development Company debentures and the sale of those debentures for over 15 years. Prior to 1986, that program was known as the 503 program. Thereafter, it became known as the 504 program.

The 503 program, like the current 504 program, provided long-term, fixed-rate financing to small firms for plant acquisition, construction, conversion or expansion, purchase of equipment and job creation. The program differed from the current 504 program chiefly because under the 503 program Development Company debentures, the proceeds of which were used to fund individual loans to small businesses, were sold to the Federal Financing Bank following SBA's guaranty. Under the 504 program, established by legislation in 1986, these same debentures are now guaranteed and pooled by SBA and purchased by private sector underwriters. Certificates backed by the pooled debentures are sold in the private markets at market interest rates.

Presently, some 3,500 503 borrowers are carrying loans with average remaining terms to maturity of 11 years and average interest rates of 10½ percent. Many borrowers would like to prepay or refinance their loans but have been precluded from doing so by the prepayment penalty clauses which were made a condition of their borrowings. Under those conditions, a 503 loan may be prepaid prior to scheduled maturity by paying an amount equal to the present value of the remaining payments of principal and interest on the loan using a discount rate based on current market yields on Treasury obligations of comparable maturities.

These regulations provide borrowers of 503 loans or issuers of SBIC or SSBIC debentures the opportunity to prepay their loans or debentures with a substitute penalty which is set forth in the following schedule based upon the original term of either the debenture which funded the 503 loan or the SBIC or SSBIC debenture, and which will be applied to the unpaid principal balance due on the debenture on the date of prepayment:

1. with respect to a 10-year term loan or debenture, 8.5 percent;
2. with respect to a 15-year term loan or debenture, 9.5 percent;
3. with respect to a 20-year term loan or debenture, 10.5 percent;
4. with respect to a 25-year term loan or debenture, 11.5 percent.

Any shortfall on the difference between the resulting payment and the original contractual premium on the debenture will be made up by SBA from funds specifically appropriated by Congress for that purpose. The terms and conditions under which prepayment may take place are explained in § 109.2–4 of these regulations, and are explicitly required by Pub. L. 103–403.

Consistent with Pub. L. 103–403, SBA will use certified mail and other reasonable means to notify each eligible issuer and borrower of the prepayment program. Each preliminary notice will specify the range and dollar amount of repurchase premiums which could be required of that issuer or borrower in order to participate in the program. In carrying out this program, SBA will provide a period of 45 days following the receipt of notice during which the issuer or borrower must notify the SBA of intent to participate in the program, at the close of which no more notifications of intent will be accepted by SBA. SBA shall require anyone who gives notice of intent to participate to make an earnest money deposit of $1,000 which shall not be refundable but which shall be credited toward the final repurchase premium.

Compliance With Executive Orders 12612, 12778, and 12866, the Regulatory Flexibility Act and the Paperwork Reduction Act

For purposes of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., SBA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

SBA certifies that this rule will not constitute a significant regulatory action for purposes of Executive Order 12866, since the change is not likely to result in an annual effect on the economy of $100 million or more.

SBA certifies that this rule will not impose additional reporting or record keeping requirements which would be subject to the Paperwork Reduction Act, 44 U.S.C. Ch. 35.

SBA certifies that this rule will not have Federalism implications warranting the preparation of a Federalism Assessment in accordance with Executive Order 12612.

SBA certifies that this rule is drafted, to the extent practicable, in accordance with the standards set forth in Section 2 of Executive Order 12778.

This rule is being published as an interim final rule because section 509(f) of Pub. L. 103–403 requires publication of a final rule within 30 days of enactment of this legislation. SBA will review any comments submitted in response to this publication before finalizing the rule. In this regard, SBA certifies that publication of this rule in accordance with the notice and comment requirements of 5 U.S.C. 553 is unnecessary or impractical because of this requirement.

List of Subjects in 13 CFR Part 109

Investment companies, Loan programs—business, Small businesses.

Accordingly, pursuant to 15 U.S.C. 636(b)(6) and 15 U.S.C. 695, et seq., SBA adds a new part 109 to title 13 of the Code of Federal Regulations as follows:

PART 109—PREPAYMENT OF SMALL BUSINESS INVESTMENT COMPANY AND CERTIFIED DEVELOPMENT COMPANY DEBENTURES

Sec.

Authority: 15 U.S.C. 636(b)(6); 15 U.S.C. 695 et seq.

§ 109.1 Purpose.

Subject to the requirements set forth in § 109.2 below, an issuer of a debenture which has been purchased by the Federal Financing Bank and guaranteed by the Small Business Administration (SBA) under the Small Business Investment Act of 1958 (Act) who has been notified of the right to make an election under these regulations, may at the election of the borrower (in the case of a loan made with the proceeds of a debenture guaranteed under section 503 of the Act or the issuer (in the case of a small business investment company) within 45 days of notification, after forwarding to SBA a nonrefundable deposit of $1,000, and with the approval of the SBA, prepay such debenture in

accordance with the provisions of this part. A small business investment company operating under the authority of section 301(d) of the Act that has issued a debenture that was purchased by and is held by the SBA, may, under the same terms and conditions, prepay such debenture, and the penalty as provided in this part.

(a) *Procedure*—(1) *In General.* In making a prepayment under § 109.1 above:

(i) The borrower (in the case of a loan made under section 503 of the Act) or the issuer (in the case of a small business investment company) shall pay to the Federal Financing Bank an amount that is equal to the sum of the unpaid principal balance due on the debenture as of the date of the prepayment (plus accrued interest at the coupon rate on the debenture) and the amount of the repurchase premium described in paragraph (a)(2) of this section; and

(ii) The SBA shall pay to the Federal Financing Bank the difference between the contractual repurchase premium paid by the borrower under this section and the repurchase premium that the Federal Financing Bank would otherwise have received on the date of repayment.

(2) *Repurchase premium.*

(i) *In general.* For purposes of paragraph (a)(1)(i) of this section, the repurchase premium is the amount equal to the product of—

(A) The unpaid principal balance due on the debenture on the date of prepayment; and

(B) The applicable percentage rate, as determined in accordance with paragraphs (a)(2) (ii) and (iii) of this section.

(ii) *Applicable percentage rate.* For purposes of paragraph (a)(2) (i)(B) of this section, the applicable percentage rate means:

(A) With respect to a 10-year term loan or debenture, 8.5 percent;

(B) With respect to a 15-year term loan or debenture, 9.5 percent;

(C) With respect to a 20-year term loan or debenture, 10.5 percent;

(D) With respect to a 25-year term loan or debenture, 11.5 percent.

(iii) *Adjustments to applicable percentage rate.* The percentage rates described in paragraph (a)(2)(B) of this section shall be increased or decreased by the SBA by a factor not to exceed one-third, if the same factor is applied in each case and if SBA determines that an adjustment is necessary, based on the number of issuers and/or borrowers having given notice of their intent to participate, in order to make the program (including the amounts appropriated for this purpose under Pub. L. 103–317) result in no substantial net gain or loss of revenue to the Federal Financing Bank or the SBA. Amounts collected in excess of the amount necessary to ensure revenue neutrality shall be refunded to the borrowers.

§ 109.2 Requirements.

For purposes of § 109.1 above, the requirements of this section are that:

(a) The debenture is outstanding and neither the loan that secures the debenture, if any, nor the debenture is in default on the date on which the prepayment is made;

(b) State, local, or personal funds, or the proceeds of a refinancing in accordance with § 109.4 are used to prepay or roll over the debenture; and

(c) With respect to a debenture issued under section 503 of the Act, the issuer certifies that the benefits, net of fees and expenses authorized by these regulations, associated with prepayment of the debenture are entirely passed through to the borrower.

§ 109.3 No prepayment fees or penalties.

No fees or penalties other than those specified in this part may be imposed on the issuer, the borrower, the SBA, or any fund or account administered by the SBA as the result of a prepayment under this part.

§ 109.4 Refinancing limitations.

(a) *In general.* The refinancing of a debenture under sections 504 and 505 of the Act, in accordance with § 109.2(b)—

(1) Shall not exceed the amount necessary to prepay existing debentures, including all costs associated with the refinancing and any applicable prepayment penalty or repurchase premium; and

(2) Except as provided in paragraphs (b) and (c) of this section shall be subject to the provisions of sections 504 and 505 of the Act and the regulations promulgated thereunder, including regulations governing payment of authorized expenses, commissions, fees, and discounts to brokers and dealers in trust certificates issued pursuant to section 505 of the Act.

(b) *Job creation.* An applicant for refinancing of a loan made pursuant to section 503 of the Act with the proceeds of the debenture funded under section 504 of the Act shall not be required to demonstrate that a requisite number of jobs will be created with the proceeds of the debenture.

(c) *Loan processing fee.* To cover the cost of loan packaging, processing, and other administrative functions, a development company that provides refinancing under § 109.2(b) above may impose a one-time loan processing fee, not to exceed 0.5 percent of the principal amount of the loan.

(d) *New debentures.* Issuers of debentures under title III of the Act may issue new debentures in accordance with such title in order to prepay existing debentures as authorized in this part.

§ 109.5 Definitions.

For purposes of this part:

(a) The term *issuer* means:

(1) The qualified State or local development company that issued a debenture pursuant to section 503 of the Act which has been purchased by the Federal Financing Bank; and

(2) A small business investment company licensed pursuant to section (c) or (d) of section 301 of the Act; or

(b) The term *borrower* means a small business concern whose loan secures a debenture issued pursuant to section 503 of the Act.

Dated: November 15, 1994.

Cassandra M. Pulley,

Acting Administrator.

[FR Doc. 94–28845 Filed 11–22–94; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM–102; Special Conditions No. 25–ANM–92]

Special Conditions; Modified Cessna Model 501 and 551 Series Airplanes, High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Cessna 501 and 551 series airplanes modified by AMR Combs, Inc., of Denver, Colorado. These airplanes are equipped with high-technology digital avionic systems that perform critical functions. The applicable type certification regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of high-intensity radiated fields (HIRF). These special conditions provide the additional safety standards that the Administrator considers necessary to ensure that the critical functions that these systems perform are maintained when the airplane is exposed to HIRF.

DATES: The effective date of these special conditions is November 16,

1994. Comments must be received on or before January 9, 1995.

ADDRESSES: Comments on these final special conditions may be mailed in duplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, Attn: Rules Docket (ANM–7), Docket No. NM–102, 1601 Lind Avenue SW., Renton, WA 98055–4056; or delivered in duplicate to the Office of the Assistant Chief Counsel at the above address. Comments must be marked "Docket No. NM–102." Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4:00 p.m.

FOR FURTHER INFORMATION CONTACT: Mark Quam, FAA, Standardization Branch, ANM–113, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, WA 98055–4056; telephone (206) 227–2145.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA has determined that good cause exists for making these special conditions effective upon issuance; however, interested persons are invited to submit such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or special conditions number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Administrator. These special conditions may be changed in light of the comments received. All comments submitted will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing such substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Persons wishing the FAA to acknowledge receipt of their comments submitted in response to this request must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. NM–102." The postcard will be date stamped and returned to the commenter.

Background

On September 28, 1994, AMR Combs, Inc., of Denver, Colorado, applied for a supplemental type certificate to modify the Cessna Model 501 and 551 series airplanes. The Model 501 and 551 airplanes are single-pilot business jets with two aft-mounted turbojet engines, capable of operating with nine and eleven passengers, respectively. The proposed modification incorporates the installation of a pilot's side Digital Electronic Flight Instrument System (EFIS), which presents critical information and annunciation to the pilot. This system is potentially vulnerable to high-intensity radiated fields (HIRF) external to the airplane.

Supplemental Type Certification Basis

Under the provisions of § 21.101 of the Federal Aviation Regulations (FAR), AMR Combs, Inc., must show that the modified Cessna Model 501 and 551 . series airplanes continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A27CE, or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis."

The regulations incorporated by reference in Type Certificate No. A27CE include the following: 14 CFR part 23 of the FAR, effective February 1, 1965, as amended by Amendments 23–1 through 23–16; and 14 CFR part 25 of the FAR, effective February 1, 1965, as amended by Amendments 25–1 through 25–17. Those sections of part 23 and part 25 that are pertinent to this installation include: § 23.1311, as amended through amendment 23–41; §§ 25.1301, 25.1303(b), and 25.1322, as amended through Amendment 25–38; and §§ 25.1309, 25.1321(a), (b), (d), and (e), 25.1331, 25.1333, and 25.1335, as amended through Amendment 25–41. In additon, the certification basis may include other amendments and findings of equivalent safety that are not relevant to these special conditions. These special conditions will form an additional part of the certification basis.

If the Administrator finds that the applicable airworthiness regulations (i.e., part 25, as amended), do not contain adequate or appropriate safety standards for the Cessna 501 and 551 series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16 to establish a level of safety equivalent to that established in the regulations.

Special conditions, as appropriate, are issued in accordance with § 11.49 of the FAR after public notice, as required by §§ 11.28 and 11.29, and become part of the type certification basis in accordance with § 21.101(b)(2).

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

Discussion

There is no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from ground based radio transmitters and the growing use of electrical and electronic systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are needed for the modified Cessna 501 and 551 series airplanes that would require that new technology electrical and electronic systems, such as the EFIS and digital avionics systems, be designed and installed to preclude component damage and interruption of function due to the effects of HIRF.

High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters, plus the advent of space and satellite communications, coupled with electronic command and control of the airplane, the immunity of critical digital avionics systems, such as the EFIS, to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling of electromagnetic energy to cockpit installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, and adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraphs 1 or 2 below:

1. A minimum threat of 100 volts per meter peak electric field strength from 10 KHz to 18 GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the following field strengths for the frequency ranges indicated.

Frequency	Peak (V/M)	Average (V/M)
10 KHz–100 KHz	50	50
100 KHz–500 KHz	60	60
500 KHz–2000 KHz	70	70
2 MHz–30 MHz	200	200
30 MHz–70 MHz	30	30
70 MHz–100 MHz	30	30
100 MHz–200 MHz	150	33
200 MHz–400 MHz	70	70
400 MHz–700 MHz	4,020	935
700 MHz–1000 MHz	1,700	170
1 GHz–2 GHz	5,000	990
2 GHz–4 GHz	6,680	840
4 GHz–6 GHz	6,850	310
6 GHz–8 GHz	3,600	670
8 GHz–12 GHz	3,500	1,270
12 GHz–18 GHz	3,500	360
18 GHz–40 GHz	2,100	750

As discussed above, these special conditions are applicable to the Cessna Model 501 and 551 series airplanes, modified by AMR Combs, Inc., of Denver, Colorado. Should AMR Combs, Inc. apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A27CE to incorporate the same novel or unusual design feature, the special conditions would apply to that model as well, under the provisions of § 21.101(a)(1).

Conclusion

This action affects only certain unusual or novel design features on the Cessna 501 and 551 series airplanes modified by AMR Combs, Inc., of Denver, Colorado. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the Cessna 501 and 551 series airplanes.

The substance of the special conditions for these airplanes has been subjected to the notice and comment procedure in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. For this reason, and because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions immediately. Therefore, these special conditions are being made effective upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. app. 1344, 1348(c), 1352, 1354(a), 1355, 1421 through 1431, 1502, 1651(b)(2), 42 U.S.C. 1857f–10, 4321 et seq; E.O. 11514; and 49 U.S.C. 106(g).

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the supplemental type certification basis for Cessna 501 and 551 series airplanes modified by AMR Combs, Inc., of Denver, Colorado.

1. *Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF).* Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high-intensity radiated fields external to the airplane.

2. The following definition applies with respect to these special conditions: *Critical Functions.* Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington, on November 16, 1994.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–28917 Filed 11–22–94; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Airspace Docket No. 94–ANM–51]

Amendment of VOR Federal Airway V–481

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the airspace designation for Federal Airway V–481 in which the Newberg radial is in error. In the airspace designation, the "Newberg 203°" radial is changed to the "Newberg 204°" radial.

EFFECTIVE DATE: 0901 UTC, February 2, 1995.

FOR FURTHER INFORMATION CONTACT: Norman W. Thomas, Airspace and Obstruction Evaluation Branch (ATP–240), Airspace-Rules and Aeronautical Information Division, Air Traffic Rules and Procedures Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–9230.

SUPPLEMENTARY INFORMATION:

The Rule

This amendment to part 71 of the Federal Aviation Regulations amends the airspace designation for Federal Airway V–481 by changing the "Newberg 203°" radial to "Newberg 204°" radial. I find that notice and public procedure under 5 U.S.C. 553(b) are unnecessary because this action is a minor technical amendment in which the public would not be particularly interested. Domestic VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.9B dated July 18, 1994, and effective September 16, 1994, which is incorporated by reference in 14 CFR 71.1. The airway listed in this document will be published subsequently in the Order.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O.10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation

Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways

* * * * *

V–481 [Revised]

From Eugene, OR, via Corvallis, OR, to INT Corvallis 351° and Newberg, OR, 204° radials.

* * * * *

Issued in Washington, DC, on November 7, 1994.

Harold W. Becker,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 94–28921 Filed 11–22–94; 8:45 am]

BILLING CODE 4910–13–P

14 CFR Part 73

[Airspace Docket No. 94–AGL–26]

Revocation of Restricted Areas R–5503 A and B; Wilmington, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action removes Restricted Areas R–5503A and B, Wilmington, OH. As a result of the base closure and realignment process, the 4950th Test Wing at Wright-Patterson Air Force Base (AFB), OH, is relocating to Edwards AFB, CA. The need for special use airspace at this location no longer exists.

EFFECTIVE DATE: 0901 UTC, February 2, 1995.

FOR FURTHER INFORMATION CONTACT: Robert Kadechka, Military Operations Program Office (ATM–420), Office of Air Traffic System Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–7683.

SUPPLEMENTARY INFORMATION:

The Rule

This amendment to part 73 of the Federal Aviation Regulations removes Restricted Areas R–5503A and B, Wilmington, OH. As a result of the base closure and realignment process, the 4950th Test Wing at Wright-Patterson AFB, OH, is relocating to Edwards AFB, CA. Because of this move, there is no longer a requirement for this special use airspace. Because this action is a minor technical amendment in which the public is not particularly interested, I find that notice and public procedure under 5 U.S.C. 553(b) are unnecessary. Section 73.55 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8B dated March 9, 1994.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This action removes special use airspace. This action is not subject to environmental assessments and procedures in accordance with FAA Order 1050.1D, "Policies and Procedures for Considering Environmental Impacts" and the National Environmental Policy Act of 1969 (NEPA).

List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510, 1522; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 73.55 [Amended]

2. Section 73.55 is amended as follows:

R–5503A Wilmington, OH [Remove]
R–5503B Wilmington, OH [Remove]

Issued in Washington, DC, on November 15, 1994

Harold W. Becker,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 94–28919 Filed 11–22–94; 8:45 am]

BILLING CODE 4910–13–P

14 CFR Part 91

[Docket Nos. 27869; 27894; 27899]

Dispositions of Noise Waiver Petitions

AGENCY: Federal Aviation Administration, DOT.

ACTION: Disposition of Noise Waiver Petitions.

SUMMARY: This document contains the dispositions of three petitions for waiver from the first compliance date under the Stage 3 transition regulations. Because of significant public interest in the filing of these petitions and the FAA's analysis of the arguments presented therein, the FAA is publishing these dispositions to disseminate its policy as established in these dispositions.

EFFECTIVE DATE: These determinations are effective November 17, 1994.

FOR FURTHER INFORMATION CONTACT: Laurette Fisher (AEE–300), Office of Environment and Energy, Federal Aviation Administration, 800 Independence Ave., SW., Washington, DC 20591; phone (202) 267–3553.

SUPPLEMENTARY INFORMATION: When the FAA promulgated the regulations requiring a transition to an all Stage 3 fleet, it established a series of three dates by which a certain level of compliance must be established; the first compliance date is December 31, 1994.

The regulations also include, in § 91.871, a provision allowing an operator to apply for a waiver from any interim compliance requirement. Section 91.871 sets out the information that must be filed by a petitioner, including a showing that a grant of a waiver would be in the public interest, the operator's plan for compliance, the petitioning operator's current financial position and fleet composition, and a showing that compliance would be financially onerous, physically impossible, technologically infeasible, or that it would have an adverse impact on competition or service to small communities.

This document sets out the FAA's dispositions of three of the first petitions for waiver received pursuant to § 91.871. Because of significant public interest in the filing of these petitions and the FAA's analysis of the arguments presented therein, the FAA is publishing these dispositions to disseminate its policy on waivers from the transition rules. Subsequent dispositions by the FAA will be published in summary form only.

Each determination was made on the basis of the filings of the individual petitioner, and thus no combined

summary of these dispositions is appropriate. These dispositions and the supporting petitions, public comments, and other documentation are available for review in the FAA Rules Docket, 800 Independence Ave., SW., Washington, DC. Dockets may be inspected in Room 915G weekdays from 9:00 a.m. to 5:00 p.m., except federal holidays.

Issued in Washington, DC on November 17, 1994.

Louise E. Maillett,

Director of Environment and Energy.

Regulatory Docket No. 27869

In the Matter of the petition of Millon Air, Inc. for a waiver from 14 CFR 91.865.

Denial of Waiver

By petition dated August 3, 1994, Suzette Matthews, Berstein & Matthews, 5649 John Barton Payne Road, Marshall, VA 22115, petitioned the Federal Aviation Administration (FAA) on behalf of Millon Air, Inc. (Millon Air), pursuant to 14 CFR 91.871 for a waiver from 14 CFR 91.865. A grant of the requested waiver would allow Millon Air to operate all of its Stage 2 airplanes beyond the interim compliance date of December 31, 1994.

The petitioner requests relief from the following regulation:

Section 91.865 requires that after December 31, 1994, each operator of Stage 2 airplanes (other than new entrant air carriers) must either reduce the number of Stage 2 airplanes it operates by 25% (to 75% of its base level) or achieve a fleet mix of airplanes that is 55% Stage 3.

The petitioner applied for relief pursuant to 14 CFR 91.871, which provides that any operator subject to § 91.865 may apply for a waiver from any interim compliance requirement, and must submit the information described in that section including the applicant's financial position, the status of its fleet and operations, the reason the waiver is necessary, and the public interest to be served in granting a waiver.

The petitioner submitted the following arguments and information in support of its request for a waiver:

Millon Air operates an all-cargo service on a charter basis worldwide and by scheduled service between the United States and Central and South America. Millon Air operates a fleet of four Stage 2 airplanes, three Boeing 707's and one McDonnell Douglas DC–8. To comply with the December 31, 1994, interim compliance date in § 91.865(b), Millon Air would need to retrofit or ground one of its airplanes. If Millon Air chooses to comply with the 55% Stage 3 fleet mix requirement of § 91.867(d), it would need to add four Stage 3 airplanes to its fleet of four Stage 2 airplanes.

The petitioner states that neither option is considered possible. First, Millon Air states that because no retrofit equipment is currently available or under development to upgrade its current airplanes to Stage 3, retrofit of one airplane is technically and physically impossible. Further, even if Stage 3 retrofit equipment were available, the cost of such equipment would, based on the cost of comparable equipment, exceed the value of the airplanes.

The petitioner also states that purchasing a replacement Stage 3 airplane would be prohibitively expensive for a carrier its size, and that such airplanes would be too costly to operate in the competitive markets in which Millon Air operates. Millon Air also states that it has been unable to locate any used aircraft that have been upgraded to Stage 3 for lease or purchase.

Millon Air states that because it operates out of Miami, Florida, taking off over water, the environmental impact of its one additional airplane would be negligible. Millon Air states that removing one aircraft from service, however, would have a significant negative impact on competition in the markets it serves. Millon Air states that it believes that the FAA should grant waivers to all operators of 707's and DC–8's for which no noise retrofit equipment is available.

Millon Air also states that a waiver would be in the public interest because there are no safety implications in continuing Stage 2 operation, and because those wishing to ship items between the United States and Central and South America have "no real alternatives to the reasonably priced air transportation provided by small operators such as Millon Air."

On September 7, 1994, the FAA sent a letter to the petitioner indicating that the agency considered the petition to be lacking certain information. Specifically, the FAA requested that the petitioner submit additional information concerning how the grant of a waiver would benefit the public as a whole, and more information on the petitioner's compliance plan and its good faith efforts to comply with § 91.865.

On September 19, 1994, the petitioner responded by reiterating the arguments presented in its original petition concerning public interest. The petitioner also stated that its compliance plans were submitted pursuant to § 91.875 as required.

On October 6, 1994, a summary of the petitioner's request was published in the **Federal Register** for public comment. Eight commenters responded to the notice, including four operators, two air carrier associations, and two airport associations. All of the commenters opposed a grant of the requested waiver.

The FAA's analysis is as follows:

The FAA has determined that the petitioner has not met the criteria outlined in 14 CFR § 91.871, and the grant of the petitioner's request for a waiver would not be in the public interest.

First, Millon Air states that it needs the requested waiver because no equipment is available to retrofit either of the airplane types it operates, Boeing 707's and a McDonnell Douglas DC–8. Accordingly, Millon Air concludes that retrofit is technically and physically impossible.

The FAA cannot accept the nonexistence of retrofit equipment as the basis for a waiver. If it did, the agency would be obligated to grant a waiver to every operator of such equipment, ostensibly for the entire interim compliance period. The FAA is confident that this was not the intent of Congress in directing a phased reduction in noise in the Airport Noise and Capacity Act of 1990; in fact, these older airplanes with no ability to be upgraded are precisely the airplanes that must be eliminated from the fleet to meet the goals established by Congress for a quieter overall aircraft operating environment. Further, by ordering a phased reduction, Congress sought to soften the economic blow of a sudden operational prohibition. To protect these airplanes until the final compliance date would not only negate the goal of the Congressional mandate, but would eliminate the expected interim noise benefits and unduly reward the actions of those operators of the oldest airplanes that chose not to invest in the newer technology that their competitors have.

To the FAA, technologically infeasible means a viable retrofit program is under active development for a particular aircraft model, and that the petitioner has committed to taking advantage of that technology as soon as it is available. The FAA would evaluate such requests in light of whether a reasonable expectation exists for certification, manufacture, delivery, and installation of that technology as put forth by the petitioner, including an evaluation of when the development program began.

To the FAA, physically impossible means while appropriate noise abatement technology exists, the petitioner is unable to achieve delivery and installation of that technology in time to meet the interim compliance date. In evaluating such a petition, the FAA would consider the amount of notice the individual petitioner had of its need for the technology, as well as the petitioner's other actions toward compliance. The FAA would not, for example, accept the argument of an established operator that, when it sought to purchase such technology in late 1994, discovered that delivery positions were not available in time to meet the December 31, 1994, compliance date.

Millon Air's circumstances do not meet either the situations outlined above, but the petition does state that Millon Air seeks only temporary relief "so it can continue to operate its aircraft until suitable retrofit or comparable replacement equipment becomes available." Millon Air also argues that there are no comparable replacements for these airplanes that can be operated as cheaply. Taken together, one conclusion would be that there will never be a suitable replacement since it is unlikely that a newer, quieter airplane would ever be cheaper to acquire and operate than those in Millon Air's current fleet; a waiver on such grounds would apparently continue indefinitely. Further, § 91.871(e) states that no waiver will be granted for a period any longer than the date of the next compliance period. Millon Air's petition does not show any expectation that the circumstances or its approach to compliance will change in that time.

As indicated previously, the FAA examines closely each petitioner's plans and actual actions toward compliance in determining whether a waiver request is reasonable and was made in good faith. In its required filings, Millon Air initially reported that it planned to meet the compliance requirements by "retirement of Stage II or addition of Stage III aircraft." In two subsequent reports, Millon Air indicated that it planned to comply in 1994 by phasing out 25% of its Stage 2 airplanes without further detail. Millon Air's petition does not contain any information as to changed circumstances or why the retirement of one airplane is no longer feasible. While Millon Air has looked into the lease or purchase of Stage 3 airplanes as an alternative, it concluded that purchase of a new airplane is financially impossible and that no used aircraft are available for purchase or lease. Accordingly, the petitioner has chosen to re-lease the same airplanes with full knowledge that the composition of its fleet would not meet the first compliance deadline.

The FAA has determined that these actions do not constitute a good faith effort to comply with the interim compliance requirements. In general, a good faith effort to comply is one in which the operator established a timely, achievable plan for compliance and made reasonable efforts to keep that plan current and follow it. Waivers will be considered for operators with such a plan that, for the reasons presented, became unable to follow that plan in time to meet the compliance date. Good faith would generally not be found when, for example, an operator's plan depends on its hope that new technology will be developed, where an operator's actions reflect no effort to investigate available options, or when an operator makes only eleventh-hour efforts that it reasonably should have known would not be successful before the compliance date at hand. In this case, the FAA has determined that no good faith effort has been demonstrated, since Millon Air has not shown a willingness even to adhere to its own compliance plan, but appears to be relying on the existence of the waiver provision to continue its current operations after the December 31, 1994, compliance date.

Finally, the FAA considers full compliance with the interim compliance requirements to be in the public interest, and any waiver granted from an interim requirement must reflect a net public benefit when weighed against noncompliance with the rule. Contrary to the statements of the petitioner, the FAA considers this balance to be more than a lack of safety impact or a negligible impact on overall noise in the petitioner's operating environment. The petitioner argues that the public would be harmed if the one airplane involved in this waiver is removed from service in the United States-South America cargo operation it offers. In presenting such an argument in a petition for waiver, the FAA would expect to see some assessment of the actual impact of diminished service that could reasonably be anticipated by the removal of the petitioner's airplane from the market. Millon Air offers no such assessment, only stating without supporting evidence that the prohibition of operation of one of its aircraft will have a "significant negative impact on competition."

The petitioner also states that cargo shippers have "no real alternatives to the reasonably priced air transportation provided by operators such as Millon Air." Again, the petitioner's statement was not accompanied by any evidence to support this assertion of current or anticipated market conditions. The statement is contradicted, however, by submissions of the commenters, including air cargo associations and other cargo carriers. In fact, by noting the existence of other similar operators, the petitioner's statement appears to contradict its own argument that removal of its single airplane will have the proffered significant effect on competition.

Finally, many of the petitioner's arguments have at their base the petitioner's choice to continue operating with the same equipment and desire not to adhere to its own compliance plan. The only reasons put forth are that no noise abatement technology has been developed by anyone else for the old airplanes it operates, and that new technology is expensive. These same factors face every operator of 707's and DC–8's, and each of these factors has been known at least since the phased compliance regulations were promulgated in 1991. The petitioner's choice to continue operating this same equipment is a business decision made with full knowledge of the regulatory requirements, and there is no public interest to be served in allowing a waiver on this basis.

Accordingly, the FAA has determined that the totality of the circumstances and arguments presented by the petitioner for a waiver from § 14 CFR 91.865 are not in the public interest.

In consideration of the foregoing, I find that the request for a waiver is not in the public interest. Therefore, by the authority delegated to me by the Administrator, the petition for a waiver by Millon Air, Inc., to § 91.865, pursuant to § 91.871, is hereby denied.

Issued in Washington, DC on November 17, 1994.

Louise E. Maillett,

Director of Environment and Energy.

Regulatory Docket No. 27899

In the Matter of the petition of AirTran Airways, Inc. for a waiver from 14 CFR 91.867.

Denial of Waiver

By petition dated September 1, 1994, AirTran Airways, Inc. (AirTran) petitioned the Federal Aviation Administration (FAA) pursuant to 14 CFR 91.871 for a waiver from 14 CFR 91.865. On September 13, 1994, in response to questions from the FAA, the petitioner submitted a supplement to its request. The requested waiver would allow AirTran to operate an all Stage 2 fleet until June 30, 1995.

The petitioner requests relief from the following regulation:

Section 91.867 requires that after December 31, 1994, each new entrant air carrier must operate a fleet that is at least 25% Stage 3.

The petitioner applied for relief pursuant to 14 CFR 91.871, which provides that any new entrant operator subject to § 91.867 may apply for a waiver from any interim compliance requirement, and must submit the information described in that section including the applicant's financial position, the status of its fleet and operations, the reason the waiver is necessary, and the public interest to be served in granting a waiver.

The petitioner submitted the following arguments and information in support of its request for a waiver:

AirTran is a subsidiary of AirTran Corporation (the Corporation). AirTran began service in June 1994 as Conquest Sun Airlines, flying passenger charters. AirTran began scheduled passenger Service in early October 1994. AirTran serves the "low fare leisure market" from the East Coast to Florida. AirTran currently operates two leased Stage 2 Boeing 737–200 airplanes. The leases for these airplanes were in place when the Corporation acquired the business in June 1994. AirTran plans to acquire two more Stage 2 737–200 airplanes in late 1994, and one more in the spring of 1995. Under § 91.867, the addition of the two airplanes in late 1994 would require one of the four airplanes in AirTran's fleet to be a Stage 3 airplane after December 31, 1994. AirTran's plans to acquire those aircraft lead to his request for a waiver.

AirTran indicates that the leases of the airplanes it currently operates do not contain provisions to hushkit those airplanes to meet Stage 3 noise levels. AirTran intends to incorporate hushkit provisions in the lease for the two additional airplanes it seeks. The petitioner notes, however, that even if the lease negotiations were already complete, no hushkit would be available until spring 1995. Although there is more than one hushkit available for the petitioner's airplane, AirTran indicates that only one of them meets its range and payloads needs, the other "creates too large an impact on fuel efficiency to be economically viable for AirTran operations." AirTran submitted a memorandum of understanding with the hushkit manufacturer that would guarantee a January 1995 delivery position, with the airplane being ready for service in the spring. The petitioner states that its research into using other aircraft models showed that they are both expensive and do not meet its business plans.

AirTran states that timing is critical in its request for this waiver. AirTran states that a waiver is critical if it is to be able to conduct its planned service, "since the winter months are the prime travel season" for the East Coast-Florida leisure market. AirTran indicates that initiation of this service in the summer months would "not be prudent" and a failure to obtain a waiver could prevent a service expansion for as long as nine months.

AirTran states that grant of a waiver would enable it to "negotiate economically viable leases on hush-kitted aircraft with proven efficiency while still providing increasing service and competition" in the market it serves. The petitioner also states that its planned transition to Stage 3 airplanes will allow it "to be in compliance with the fifty percent Stage 3 deadlines of December 31, 1996." For these reasons, the petitioner states, a grant would be in the public interest.

On October 6, 1994, a summary of the petitioner's request was published in the **Federal Register** for public comment. Seven commenters responded to the notice, including two airport associations, four operators, and one national environmental organization. All of the commenters opposed a grant of the requested relief.

The FAA's analysis is as follows:

The FAA has determined that a grant of the petitioner's request for a waiver would not be in the public interest.

First, it is FAA policy to consider for the possibility of waiver only those airplanes in operation by an operator on the date of the petition. In this instance, the operator has not yet leased the airplanes for which it requests a waiver.

When the Corporation acquired the former Conquest Sun Airlines in June 1994, it was, or should have been, well aware of the requirements for new entrants in § 91.867 and the status of the leased airplanes it acquired in the transaction. The basis for its request, then, is not that its circumstances somehow changed from its planned means of compliance, but appears to be its own business plan to acquire two more Stage 2 airplanes by the end of the year.

In the Airport Noise and Capacity Act of 1990, which gave rise to the compliance schedule in § 91.867, Congress mandated that there be an analysis of the impact of any compliance schedule "on new entry into the airline industry." As a result of this mandate, the FAA promulgated a rule that gave new entrants a less stringent compliance schedule that was based on the perceived need to be adding new airplanes to their fleets. The FAA does not interpret this mandate as requiring the FAA to accept the business plans of new entrants that call for operation of Stage 2 airplanes past any compliance date, especially when the new entrant makes those plans and begins service just a few months before a compliance date. In this case, the petitioner would be free to add a third Stage 2 airplane to its fleet without any further action. It is the fourth airplane, not yet leased, that the petitioner would need to make Stage 3 before it operates. Although the petitioner has not yet leased this airplane, it is apparantly unwilling to adapt its business plans to use only that level of service it can achieve in compliance with a regulation that predates the existence of the airline.

Since the petitioner is a new entrant, it does not yet have a compliance plan on file. The petition gives little information as to the petitioner's planned compliance, other than to say it can afford the necessary hushkit and is in the early stages of contracting for it, to be installed on an airplane that is not yet leased. The petitioner has submitted no information why its current business plan does not take into account the upcoming compliance date without asking for a waiver. As part of its annual compliance report, if any operator were to submit as its compliance plan that it planned to ask for a waiver, the FAA could not find that the operator's plan was made in good faith; the petitioner exhibits the same lack of good faith by sticking to its business plan for an airline acquired in June 1994.

The FAA has determined that, taken together, these circumstances do not exhibit a good faith attempt to comply with the regulation, as required in § 91.871.

Moreover, the petitioner fails to state any reasonable public interest that would be served by granting the requested relief, if it were available. The FAA considers full compliance with the interim compliance requirements to be in the public interest, and any waiver granted from an interim requirement must reflect a net public benefit when weighed against noncompliance with the rule. The petition states only that the waiver would enable the petitioner to negotiate better leases on hushkitted airplanes "while still providing increasing service and competition East Coast markets to Florida," and that it will assist the petitioner in achieving "compliance with the fifty percent Stage 3 deadline" in 1996.

The waiver provision was not promulgated to assist any operator in

achieving better business deals, nor is it clear how a denial of this waiver could affect the petitioner's compliance in 1996. Further, the FAA will consider waivers based on *reduced* competition when a petitioner presents an assessment of the affected market if a waiver were not granted. In this case, the market will not change from its current status if the waiver is not granted. The waiver provision does not exist for the purpose of increasing competition. The FAA does not accept the argument that every airplane in a particular market represents competition, and therefore it is in the public interest to maximize that number at all costs. To allow such reasoning would be unfair to the competing operators in the market that have already complied with the same requirements the petitioner seeks to avoid. Increased competition does not outweigh the public's interest in compliance with the regulations or the accompanying reduction in noise levels anticipated by the Congress and the public when the regulations were adopted in 1991. These arguments are reiterated by the commenters to this petition, one of which is a new entrant in a similar market that is already in compliance with the rule.

Accordingly, the FAA has determined that the arguments presented by the petitioner reflect neither a good faith attempt to comply with the regulations nor any convincing statement of public interest in a grant of the requested waiver.

In consideration of the foregoing, I find that the request for a waiver is not in the public interest. Therefore, under the authority delegated to me by the Administrator, the petition for a waiver by AirTran Airways, Inc., to § 91.865, pursuant to § 91.871, is hereby denied.

Issued in Washington, DC on November 17, 1994.

Louise E. Maillett,

Director of Environment and Energy.

Regulatory Docket No. 27894

In the Matter of the petition of AirTran Corporation for a waiver from 14 CFR 91.867.

Denial of Waiver

By petition dated August 29, 1994, AirTran Corporation (AirTran) petitioned the Federal Aviation Administration (FAA) pursuant to 14 CFR 91.871 for a waiver from 14 CFR 91.855 and 91.865. The requested waiver would allow AirTran to import Stage 2 airplanes from foreign markets, and begin and continue operation with an all Stage 2 fleet beyond the interim compliance date of December 31, 1994.

The petitioner requests relief from the following regulations:

Section 91.855 prohibits the operation in the contiguous United States of any Stage 2 airplane that was not U.S.-owned on November 5, 1990.

Section 91.867 requires that after December 31, 1994, each new entrant must operate a fleet that is at least 25% Stage 3.

The petitioner applied for relief pursuant to 14 CFR 91.871, which provides that any new entrant operator subject to § 91.867 may apply for a waiver from any interim compliance requirement, and must submit the information described in that section including the applicant's financial position, the status of its fleet and operations, the reason the waiver is necessary, and the public interest to be served in granting a waiver.

The petitioner submitted the following arguments and information in support of its request for a waiver:

AirTrain does not currently own or operate any aircraft. Its planned service includes daily passenger flights between Pittsburgh, Philadelphia, and Detroit. On January 24, 1994, AirTrain was granted a Certificate of Public Convenience and Necessity by the Department of Transportation. That certificate is not yet effective, pending AirTrain's receipt of an air carrier certificate, not yet issued by the FAA.

AirTrain indicates that its strategic business plan calls for it to provide the planned service using McDonnell Douglas DC–9 aircraft exclusively. The petitioner's efforts to locate any suitable DC–9 30/40 series airplanes domestically has been unsuccessful, but it has located several of them overseas that it can "more realistically afford at this stage as a new entrant." The petitioner is aware that § 91.855 prohibits the operation of imported airplanes, and seeks relief from that section. The petitioner also states that to have 25% of its airplanes be Stage 3 after December 31 of this year "would be financially onerous to it as a new entrant, and in addition be physically impossible to accomplish before December 31, 1994, even if it were not financially onerous," and thus seeks a waiver from that requirement as well.

The petitioner did not submit a current balance sheet and cash flow statement as required by § 91.871(c)(1), stating that the information was not available.

The petitioner states that a grant of the requested relief would be in the public interest because the public has an unfulfilled need for the contemplated service, because the commencement of operations will create jobs in the market cities, because the contemplated service will be an economical alternative for travel between the market cities, because failure to grant the requested relief would have an adverse effect on competition since the public would be "deprived of an additional mode of transportation" between the market cities, because failure to provide the requested relief would have an adverse effect on service to small communities surrounding the market cities, and because failure to grant the requested relief would "severely limit competition and free market pricing of air fares" in the market.

On August 31, 1994, the petitioner supplemented its original request by submitting an updated copy of its Certificate of Public Convenience and Necessity.

On October 6, 1994, a summary of the petitioner's request was published in the **Federal Register** for public comment. Seven commenters responded to the notice, including two airport associations, four operators, and one national environmental organization. All of the commenters opposed a grant of the requested relief.

The FAA's analysis is as follows:

The FAA has determined that the petitioner has not met the criteria outlined in 14 CFR 91.871, and that grant of the petitioner's request for a waiver and other relief is not within FAA's authority and would not be in the public interest.

The request for relief from § 91.855 is inappropriate. The prohibition on the operation of foreign-owned aircraft purchased by a U.S. person in the contiguous United States is contained in § 9309 of the Airport Noise and Capacity Act of 1990 (ANCA) and is known as the nonaddition rule. The only exemption allowed under ANCA is for an imported Stage 2 airplane to be brought into the United States to obtain modifications to meet Stage 3 noise levels. The principles of that prohibition were incorporated into § 91.855, but the FAA has no authority to go beyond the single exemption found in the ANCA. Simply, the FAA cannot grant the relief requested—to permit operation of an imported Stage 2 airplane in the contiguous United States. The waiver provision of § 91.871 by its terms applies only to the interim compliance requirements of § § 91.865 and 91.867.

Even if the petitioner were able to acquire airplanes domestically, its petition would fail for other reasons. First, it is FAA policy to consider for the possibility of waiver only those airplanes in operation by an operator on the date of the petition. In this instance.

the petitioner does not have any airplanes in operation.

Second, it is also FAA policy that no prospective relief be granted. Section 91.851 defines "new entrant" as an air carrier that begins operating after November 5, 1990. Since the petitioner has not yet achieved FAA certification to operate, it is not yet operating under the provisions of § 91.867 to be considered a new entrant or to ask relief from that regulation.

Further, even if the petition were not inappropriate for these reasons, it would still fail on it merits. The primary basis of the petitioner's argument is its "strategic business plan" that calls for the operation of one type of aircraft. The petitioner has noted that such airplanes are not available domestically, but has chosen to remain with that plan and seek exemption from a legislative prohibition. The petition does not contain the required financial information or any other data concerning acquisition costs to support its statement that compliance would be financially onerous. Since the petitioner claims to be a new entrant, it does not have a compliance plan on file, but neither does the petition include the petitioner's plan for compliance nor any evidence of how the petitioner would meet future interim compliance requirements were the requested relief granted.

The FAA has determined that, taken together, these arguments demonstrate neither reasonableness nor good faith in applying for a waiver. Instead of changing its business plan to meet the requirements of a regulation that has been in place since 1991, the petitioner has requested that it be grandfathered into the compliance schedule as if it had begun operation already, and then asks that that relief be extended beyond what would be required if it had commenced operations. Simply put, if the petitioner cannot affort to commence operation according to the regulations, the FAA can have little expectation that the petitioner will ever be able to comply, and the only good faith action is for the petitioner to adjust its business plans accordingly, a course of action that the petitioner has already expressed it is unwilling to take.

Moreover, the petitioner fails to state any reasonable public interest that would be served by granting the requested relief, if it were available. The FAA considers full compliance with the interim compliance requirements to be in the public interest, and any waiver granted from an interim requirement must reflect a net public benefit when weighed against noncompliance with the rule. The petitioner has stated but not shown that there is an "unfulfilled need" for the contemplated service between Philadelphia, Pittsburgh, and Detroit, but the data it submitted regarding the current available service rebuts this. While the petitioner states that its contemplated service will be at much lower fares than currently available, the only evidence is the petitioner's plan to charge less and its general statements that dramatic fare reductions have been achievable by other carriers in other markets.

Taken as a whole, these general statements are not convincing that the waivers required to achieve this contemplated service in any manner outweighs the public interest in a quieter environment as established by Congress and in compliance with the regulations in general. The petitioner has not presented any logical evidence how the failure to grant relief could have a negative impact on competition or fares, since the petitioner is not yet offering any competing service nor has it presented evidence that it will be able to operate for lower fares; as yet, there are no aircraft on which to even base cost estimates. The petitioner's claim of adverse effect on service to small communities surrounding the market cities is oxymoronic, since considerations of service to small communities have historically had no relation to service from the closest large cities. Finally, to allow the petitioner to begin operation without being subject to the same rules under which its competition operates would be markedly unfair to the operating carriers in those markets who have met the requirements with the same notice and market conditions affecting the petitioner.

Accordingly, the FAA has determined that the petitioner's requested relief from § 91.855 is outside the authority of the FAA to grant, that its petition requesting relief under § 91.867 is inappropriate given its lack of certification and current operation, and that the arguments presented in its petition do not reflect a good faith attempt to comply with the regulations and are not in the public interest.

In consideration of the foregoing, I find that the request for a waiver is not in the public interest. Therefore, by the authority delegated to me by the Administrator, the petition for a waiver by AirTran Corporation to § 91.865, pursuant to § 91.871, is hereby denied.

Issued in Washington, DC on November 17, 1994.

Louise E. Maillett,

Director of Environment and Energy.

[FR Doc. 94-28916 Filed 11-18-94; 3:36 pm]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 358

[Docket No. 80N-0238]

RIN 0905-AA06

Wart Remover Drug Products for Over-the-Counter Human Use; Amendment of the Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the final monograph for over-the-counter (OTC) wart remover drug products to revise the directions for products containing 15 percent salicylic acid in a karaya gum, glycol plaster vehicle. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: November 23, 1995.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 1990 (55 FR 33246), FDA issued a final monograph for OTC wart remover drug products (21 CFR part 358). The final monograph included in § 358.110(c) (21 CFR 358.110(c)) products containing 15 percent salicylic acid in a karaya gum, glycol plaster vehicle. Such products were included in the monograph based on the agency's evaluation of data from three clinical studies (Ref. 1). (See comment 13, 55 FR 33246 at 33253.) The directions for such products were included in § 358.150(d)(3) (21 CFR 358.150(d)(3)) as follows:

"Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly." (If appropriate: "Cut plaster to fit wart.") "Apply medicated plaster at bedtime, leave in place for at least 8 hours; in the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

In discussing the labeling for these products (also in comment 13), the agency stated:

If there are any special directions that relate to using a particular product, then such information should appear as part of the manufacturer's additional directions for the product. The monograph provides the minimum directions necessary for use of the product. Manufacturers may supplement these directions with additional information necessary to use their specific product. For example, the agency notes that the manufacturer's directions for its specific product include statements to "keep plastic film on the top of pad facing up and to apply sticky bottom side to the wart." The agency finds no need to include such directions in this final monograph; however, manufacturers may add such information, as appropriate, to the labeling of their products.

Subsequently, the agency became aware that a manufacturer of this product had the following additional statements in its product's labeling (Ref. 2): (1) "Smooth wart surface with emery file supplied," and (2) "Apply a drop of warm water to the wart, keeping the surrounding skin dry." The agency has rereviewed the clinical studies (Ref. 1) for this product and determined that this additional labeling information is based on the manner in which the clinical studies were performed. The agency notes that use of an emery file and application of a drop of warm water to the wart site as part of the directions for this type of product were not included in the labeling suggestions made by the manufacturer when the final monograph was being prepared (see comment 13, 55 FR 33246 at 33253).

The agency is concerned that similar products in the marketplace may have different directions—some recommending use of an emery file and a drop of warm water to prepare the wart site and others not mentioning use of an emery file and a drop of warm water. Because of concerns that this situation could lead to consumer confusion, in the **Federal Register** of January 28, 1994 (59 FR 4015), the agency proposed to amend the final monograph for OTC wart remover drug products to revise the directions for products containing 15 percent salicylic acid in a karaya gum, glycol plaster vehicle. The agency proposed that the directions in § 358.150(d)(3) be revised to read as follows:

"Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly. Gently smooth wart surface with emery file supplied." (If appropriate: "Cut plaster to fit wart.") "Apply a drop of warm water to the wart, keeping the surrounding skin dry. Apply medicated plaster at bedtime and leave in place for at least 8 hours. In the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

References

(1) Comment No. RPT2, Docket No. 80N–0238, Dockets Management Branch.

(2) Labeling for Trans-Ver-Sal, included in OTC Vol. 16CFMA, Docket No. 80N–0238, Dockets Management Branch.

Interested persons were invited to submit written comments by March 29, 1994. One manufacturer of OTC wart remover drug products submitted a comment in response to the agency's proposal. Copies of the comment are on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

The manufacturer stated that it marketed a 15 percent salicylic acid in karaya gum product in a glycol plaster vehicle. The comment agreed with the agency's proposal and commended the agency's efforts in updating the product directions to be consistent with the original clinical methods used during its development. The comment stated that this revision to include use of an emery file and a drop of water is in keeping with the long marketing history of this product.

The comment pointed out that some mild abrasion is unavoidable while preparing the treatment site with the emery file and that the karaya gum vehicle minimizes the potential for irritation associated with any such abrasion. The comment added that the drop of water helps facilitate the initiation of the keratolytic action when the salicylic acid is applied.

The agency appreciates the comment's support. Accordingly, the agency is finalizing the proposed revised directions in § 358.150(d)(3) for 15 percent salicylic acid in a karaya gum, glycol plaster vehicle identified in § 358.110(c).

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (59 FR 4015 at 4016). FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this rulemaking is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule will impose direct one-time costs associated with changing product labels for OTC wart remover drug products containing 15 percent salicylic acid in a karaya gum, glycol plaster vehicle. There are only a few such products in the marketplace. Relabeling should be a nominal cost, and manufacturers will have 1 year after publication of this final rule to implement this labeling. Thus, this rulemaking for OTC wart remover drug products is not expected to have an impact on small businesses. Accordingly, the agency certifies that this amendment to the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

As discussed in the proposal (59 FR 4015 at 4016), the agency advised that any final rule resulting from the proposed rule would be effective 12 months after its date of publication in the **Federal Register**. Therefore, on or after November 23, 1995, any OTC wart remover drug product that is not in compliance with this final rule may not be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application or abbreviated application. Further, any OTC drug product subject to this final rule that is repackaged or relabeled after the effective date of the rule must be in compliance with the rule regardless of the date that the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the final rule at the earliest possible date.

List of Subjects in 21 CFR Part 358

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 358 is amended as follows:

PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 358 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 358.150 is amended by revising paragraph (d)(3) to read as follows:

§ 358.150 Labeling of wart remover drug products.

* * * * *

(d) * * *

(3) *For products containing salicylic acid identified in § 358.110(c).* "Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly. Gently smooth wart surface with emery file supplied." (If appropriate: "Cut plaster to fit wart.") "Apply a drop of warm water to the wart, keeping the surrounding skin dry. Apply medicated plaster at bedtime and leave in place for at least 8 hours. In the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

* * * * *

Dated: November 8, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94–28857 Filed 11–22–94; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 870

Abandoned Mine Reclamation Fund—Fee Collection and Coal Production Reporting

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of suspension.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) of the United States Department of the Interior (DOI) is suspending a portion of its permanent program regulations found at 30 CFR 870.5 which defines the term *Qualified hydrologic unit.* This action is being taken in order to assure that the language of this definition comports with the language of Title IV of the Surface Mining Control and Reclamation Act (SMCRA) of 1977, as amended by the Omnibus Budget Reconciliation Act of 1990 (November 5, 1990) which included the Abandoned Mine Reclamation Act of 1990, as amended, and by the Energy Policy Act of 1992 (October 24, 1992).

EFFECTIVE DATE: November 23, 1994.

FOR FURTHER INFORMATION CONTACT: Norman J. Hess, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1951 Constitution Avenue, N.W., Washington, DC 20240, Telephone: 202–208–2949.

SUPPLEMENTARY INFORMATION:

I. Background

The Abandoned Mine Land (AML) Reclamation Program was established by SMCRA, Public Law 95–87, 30 U.S.C. 1201 et seq., in response to concern over extensive environmental damage caused by past coal mining activities. On October 25, 1978, OSM published final regulations implementing an AML Reclamation Program incorporating the provisions of Title IV of SMCRA. OSM published revisions to these regulations on June 30, 1982, in response to the Administration's request for regulatory review. On November 5, 1990, the President signed into Law the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508, which included the Abandoned Mine Reclamation Act of 1990, as amended. In addition to extending the authority to collect reclamation fees, the amendments to Title IV contained several significant provisions. OSM published proposed rules at 56 FR 57376–57401 (November 8, 1991) implementing the 1990 amendments to Title IV of SMCRA and requested comments from the public. On October 24, 1992, the President signed into law the Energy Policy Act of 1992, Public Law 102–486. Included in this law were several additional amendments to the AML Reclamation Program under Title IV of SMCRA. These amendments were incorporated into the rulemaking and the Abandoned Mine Land Reclamation Fund Reauthorization Implementation final regulations were published at 59 FR 28136–28174 (May 31, 1994).

II. Discussion of Definition Suspended

The final rule noted above amended the definitions in Section 870.5 for "eligible lands and water," and "left or abandoned in either an unreclaimed or inadequately reclaimed condition," and added new definitions for "mineral owner" and "qualified hydrologic unit." The new definitions updated these terms so that they would be consistent with the recent amendments to SMCRA. The definitions reflect additional eligibility for lands adversely affected by mining between August 3, 1977 and November 5, 1990; for noncoal lands after certification of the reclamation of all known coal problems; for water projects; and finally for lands affected by qualifying operations.

The term *Qualified hydrologic unit* has been defined at Section 870.5 of the final regulation. Statutory language contained in SMCRA Section 402(g)(7)(D) stipulates that a qualified hydrologic unit must include lands and waters which are eligible pursuant to Section 404 and include any of the first three priorities as stated in Section 403(a), *and* (2) proposed to be the subject of expenditures by the State/Indian tribe (from amounts available from the forfeiture of bonds required under Section 509 or from other State/Indian tribe sources) to mitigate acid mine drainage. In Section 870.5 of the regulation, OSM substituted *or* for *and* thereby making both categories independently eligible for funding. Concern has been raised as to whether the language of the regulation is consistent with the language of the statute in that it inappropriately broadens the definition beyond that allowed by the statute. Due to this concern, the definition of *Qualified hydrologic unit* contained in Section 870.5 of the regulations is suspended in so far as it does not require a hydrologic unit to be both (1) eligible pursuant to Section 404 and include any of the first three priorities stated in Section 403(a), and (2) proposed to be the subject of expenditures by the State (from amounts available from the forfeiture of a bond required under Section 509 or from other State sources) to mitigate acid mine drainage in order to be considered a qualified hydrologic unit.

III. Procedural Matters

Federal Paperwork Reduction Act

This Notice of Suspension does not contain collections of information which require approval by the Office of Management and Budget under 44 U.S.C. 3501 et seq.

Executive Order 12866

This Notice of Suspension has been reviewed under Executive Order 12866.

Regulatory Flexibility Act

DOI has conducted an analysis of the underlying final regulations published at 50 FR 28136–28174 (May 31, 1994) and determined, pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., that the final rule will not have a significant economic impact on a substantial number of small entities. The legislation enacted by Congress extends an existing program, and the resulting costs to the regulated industry and to consumers are not expected to vary from current levels. Further, it has also been determined that this Notice of Suspension will have no material effect on small business entities.

National Environmental Policy Act

The effect of the regulation being suspended by this Notice of Suspension was included in an environmental assessment (EA) prepared by OSM for the underlying final regulations. That EA made a finding that the final regulations would not significantly effect the quality of the human environment under Section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C). The EA and finding of no significant impact are on file in the OSM Administrative Record, room 660, 800 N. Capitol St., NW., Washington, DC.

Author

The principal author of this Notice of Suspension is Norman J. Hess, Division of Abandoned Mine Land Reclamation, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1951 Constitution Avenue NW., Washington, DC 20240; Telephone: 202–208–2949.

List of Subjects

30 CFR Part 870

Reporting and recordkeeping requirements, Surface mining, Underground mining.

Dated: October 28, 1994.

Bob Armstrong,

Assistant Secretary, Land and Minerals Management.

Accordingly, a portion of the definition of Qualified hydrologic unit contained in 30 CFR 870.5 is suspended as set forth below:

PART 870—ABANDONED MINE RECLAMATION FUND—FEE COLLECTION AND COAL PRODUCTION REPORTING

1. The authority citation for Part 870 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; and P.L. 100–34.

§ 870.5 [Partially Suspended]

2. The definition of Qualified hydrologic unit contained in § 870.5 Definitions is suspended in so far as it does not require a hydrologic unit to be both: (1) Eligible pursuant to Section 404 and include any of the first three priorities stated in Section 403(a), and (2) proposed to be the subject of expenditures by the State (from amounts available from the forfeiture of a bond required under Section 509 or from other State sources) to mitigate acid mine drainage in order to be considered a qualified hydrologic unit.

[FR Doc. 94–28937 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–05–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MI24–02–6743; FRL–5111–1]

Approval and Promulgation of State Implementation Plan; Michigan; Miscellaneous Rule Changes, Technical Changes

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Final rule.

SUMMARY: On September 15, 1994, the USEPA published simultaneous proposed and final rules partially approving and partially disapproving a revision to the Michigan State Implementation Plan (SIP) incorporating technical changes to miscellaneous air control rules. On October 17, 1994, the State withdrew the parts of its submittal which USEPA disapproved. In response, this notice reclassifies the September 15, 1994 action as a full approval.

EFFECTIVE DATES: This rule becomes effective on November 23, 1994.

ADDRESSES: Copies of the State's submittals and USEPA's analysis are available for inspection at the U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (Please telephone Megan Beardsley at (312) 886–0669 to arrange an appointment before visiting the Region 5 office.)

Copies of the State's submittals also are available at the Office of Air and Radiation, Docket and Information Center (Air Docket 6102), Room M1500, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 260–7548.

FOR FURTHER INFORMATION CONTACT: Megan Beardsley, Environmental Scientist, Regulation Development Section, Air Toxics and Radiation Branch (AT–18J), U.S. Environmental Protection Agency, Region 5, Chicago, Illinois 60604, (312) 886–0669.

SUPPLEMENTARY INFORMATION:

On November 12, 1993, the State of Michigan requested that the USEPA revise its SIP to incorporate a number of technical rule changes that the State adopted in 1989. Most of these changes were minor, clarifying rules or removing definitions of terms no longer used in Michigan law, but some changes were more substantial. None of the changes were required by the Clean Air Act (the Act) or other Federal law or policy. However, because the State requested that USEPA incorporate the changes into the SIP, USEPA reviewed the changes to assure that they were in accordance with the Act. Most of the changes submitted by the State clarified and strengthened the SIP, but several were not approvable.

On September 15, 1994, in accordance with Agency procedures for "direct final" rulemaking (see April 2, 1994 memorandum from Jerry M. Stubberfield, Acting Chief, Regional Operations Branch, to Air Branch Chiefs, "State Implementation Plan (SIP) Direct Final Processing Procedures"), the USEPA published simultaneous proposed and final rules (59 FR 47287 and 59 FR 47254). These rules partially approved the State's submittal and provided a public comment period ending October 17, 1994. Because notice of intent to submit adverse comments was not received by October 17, 1994, the rulemaking took effect on November 14, 1994. However, on October 17, 1994, the State of Michigan withdrew those parts of the submittal which USEPA had disapproved. Thus, USEPA must change the classification of the September 15, 1994 rulemaking from "partial approval/partial disapproval" to "full approval." That is the purpose of this action.

Since the distinction between full and partial approval was made only in the preambles to the September 15, 1994 notices, the Michigan withdrawal and this action in no way affect the amendment of the Michigan SIP which USEPA codified in the September 15, 1994 final rule. That amendment became effective, as scheduled, on November 14, 1994.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen oxides, Ozone, Volatile organic compounds.

Authority: 42 U.S.C. 7401–7671q.

Dated: November 2, 1994.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 94–28877 Filed 11–22–94; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 8

[FAR Case 93–613; FAC 90–21 Corr.]

Federal Acquisition Regulation; Multiple-Award Schedules Ordering Procedures; Technical Correction

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Technical correction.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council are issuing a correction to FAR case 93–613, Multiple-Award Schedules (MAS) Ordering Procedures which appeared in FAC 90–21 published on October 25, 1994, at 59 FR 53716. At FAR 8.404 text was omitted from paragraph (c)(1), and (c)(2) was corrected by removing the "(i)" designation as well as paragraph (ii).

EFFECTIVE DATE: October 25, 1994.

FOR FURTHER INFORMATION CONTACT: Ms. Linda Klein at (202) 501–3775.

PART 8—REQUIRED SOURCES OF SUPPLIES AND SERVICES

On page 53717, first and middle columns, in section 8.404 paragraphs (c)(1) and (2) are correctly set forth to read as follows:

8.404 Using schedules.

* * * * *

(c) *Mandatory use.* (1) This paragraph (c) applies only to orders against schedule contracts with mandatory users. When ordering from multiple-award schedules, mandatory users shall also follow the procedures in paragraphs (a) and (b) of this section.

(2) In the case of mandatory schedules, ordering offices shall not solicit bids, proposals, quotations, or otherwise test the market solely for the purpose of seeking alternative sources to Federal Supply Schedules.

* * * * *

Albert A. Vicchiolla,

Director, Office of Federal Acquisition Policy, General Services Administration.

[FR Doc. 94–28722 Filed 11–22–94; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Chapter III and Parts 382, 390, 391, 392, 395, and 396

[FHWA Docket No. MC–93–32]

RIN 2125–AD28

Removal of Obsolete and Redundant Regulations and Appendices

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is removing regulations and appendices from the Federal Motor Carrier Safety Regulations which are obsolete, redundant, or more appropriately regulated by State and local authorities. This action is in response to the FHWA's Zero Base Regulatory Review.

EFFECTIVE DATE: December 23, 1994; except for revisions to §§ 391.68 and 391.73 which will become effective on January 2, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. Peter C. Chandler, Office of Motor Carrier Standards, (202) 366–5763, or Mr. Charles E. Medalen, Office of Chief Counsel, (202) 366–1354, Federal Highway Administration, Department of Transportation, 400 Seventh Street, SW, Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

The first Federal Motor Carrier Safety Regulations (FMCSRs) were promulgated in 1937. The FMCSRs have been amended many times during the past 57 years. In September 1992, the FHWA began a comprehensive multi-year project to develop modern, uniform safety regulations that are up to date, clear, concise, easier to understand, and more performance oriented. This project has been named the "Zero Base Regulatory Review."

Upon the announcement of the first four "Zero Base" public outreach sessions in the **Federal Register** (57 FR 37392) on August 18, 1992, the FHWA opened a public docket, MC–92–33, to allow interested parties who were unable to attend an outreach session the opportunity to submit comments and recommendations for improvement of the FMCSRs. After the comment period closed on April 1, 1993, and the comments were analyzed, the FHWA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (59 FR 1366) on January 10, 1994, proposing to remove specific regulations and appendices from the FMCSRs. Some designated sections of the FMCSRs and all designated appendices were identified as obsolete or redundant of other sections of the FMCSRs. Other designated sections of the FMCSRs were identified as duplicative of State or local regulations and were considered to be more appropriately regulated by State and local authorities. Technical amendments to part 391 of the FMCSRs were also proposed in the NPRM.

The FHWA received twenty comments to the docket. Ten were from associations, six from motor carriers, two from consulting companies, and one each from a State agency and an individual. Eight of the commenters supported all of the proposed changes; however, the Advocates for Highway and Auto Safety opposed all of the proposed changes. Other commenters supported some proposed changes and opposed others, or made recommendations or commented on matters not related to this rulemaking. The following is a discussion of the comments to the docket, along with the FHWA's response, arranged by part and section of the FMCSRs.

PART 382—CONTROLLED SUBSTANCES AND ALCOHOL USE AND TESTING

Paragraph (6) of the definition of *On duty time* in § 395.2 is being removed which is explained below in part 395. This removal necessitates a technical amendment to the definition of *Safety-sensitive function* in § 382.107 because the definition references paragraphs (1) through (7) of the definition of *On duty time*. The definition of *Safety-sensitive function* is being amended to reference paragraphs (1) through (6) of the definition of *On duty time*.

PART 391—QUALIFICATIONS OF DRIVERS

The FHWA proposed to remove all requirements pertaining to the written examination and record of violations. The FHWA also proposed to remove a paragraph from the limited exemption

for drivers operating in the State of Hawaii.

Written Examination

Ten commenters supported and six commenters opposed the removal of the requirements related to the written examination. Four commenters expressed concern that the removal of the written examination requirements would result in a lack of instruction for drivers not subject to the commercial driver's license (CDL) requirements. Two commenters recommended that the written examination requirements be strengthened, such as, by establishing a passing grade. The American Trucking Associations, Inc. (ATA), argued that a driver-applicant could file suit for discrimination if denied employment for refusing to take a written examination administered as a company policy, rather than as a Federal requirement.

FHWA Response: The removal of the requirements related to the written examination would have very little effect on highway safety while reducing the paperwork burden imposed upon motor carriers. The objective of the written examination is to instruct prospective drivers in the FMCSRs. There is no passing score and even a poor performance does not prohibit a motor carrier from hiring the driver. The removal of the written examination would not affect the motor carrier's obligation under 49 CFR 390.3(e)(2) to instruct drivers and employees about the FMCSRs.

The programs of the FHWA have made commercial motor vehicle (CMV) drivers more familiar with the FMCSRs than was the case in previous decades. Motor carriers are now in a better position than the FHWA to decide whether the written examination remains a useful instructional tool. On the other hand, drivers are required to pass a knowledge test to obtain a CDL. Although the material covered by the written examination and the CDL knowledge test is not exactly the same, there is some overlap. In consideration of these circumstances, the benefits of the written examination are outweighed by the paperwork burden it imposes on motor carriers. Motor carriers may continue to administer the written examination as a part of their training program, but the FHWA will no longer require them to do so.

Retaining and strengthening the written examination by establishing a passing grade would impose a prescriptive method upon motor carriers to instruct their drivers and employees about the FMCSRs. One thrust of the Zero Base Regulatory Review is to make the FMCSRs more performance oriented to provide motor carriers with increased flexibility in achieving compliance. The removal of the written examination is a good example of this intention.

The FMCSRs are not intended to reinforce or support every action a motor carrier might take in hiring or qualifying its drivers. Motor carriers have long been allowed to require or enforce more stringent safety or health standards than those required by the FMCSRs [49 CFR 390.3(d)]. Motor carriers that continue to administer the written examination or similar test under company policy should face no increased potential liability as long as all applicants are treated in the same manner. Such a policy would only rarely be affected by the Rehabilitation Act of 1973 (Pub. L. 93–112, 87 Stat. 355, as amended) or the Americans with Disabilities Act of 1990 (Pub. L. 101–336, 104 Stat. 327, as amended).

The written examination (contained in appendix C) and all related qualification and recordkeeping requirements are removed. The sections affected by this removal include §§ 391.11(b)(11); 391.35; 391.37; 391.51(c)(5); 391.51(d)(3); 391.61; 391.67(a); 391.67(c); 391.68; 391.69(b); 391.71(a); 391.73 and appendix C to subchapter B.

Record of Violations

Nine commenters supported and eight opposed the removal of all requirements related to the record of violations. American Insurance Service Group, Inc., Engineering and Safety Service had no objection to the removal of the record of violations provided motor carriers were required to make an inquiry annually into their drivers' driving records to the license issuing State agency. Carrier Compliance Services opposed the removal of the record of violations and recommended that motor carriers also be required to make an annual inquiry into their drivers' driving records. Tandem Transport, Inc., recommended that a motor carrier be allowed the option of making an annual inquiry into a drivers' driving record or requiring the driver to furnish it with a record of violations annually. Three commenters argued that, although CDL holders must notify their employers within 30 days of any conviction for a non-parking violation in any type of motor vehicle, the record of violations provision is the only notification requirement applicable to drivers of smaller motor vehicles, and that its removal would therefore eliminate an important source of information.

FHWA Response: The FHWA has decided not to remove the requirements related to the record of violations at this time. The FHWA will further evaluate the submitted recommendations and determine whether a rulemaking action to amend the current requirements is warranted.

Drivers Operating in Hawaii

No commenters expressed specific opposition to the removal of § 391.69(a).

FHWA Response: Section 391.69(a) states that "drivers who will reach the age of 21 no later than April 1, 1976, may continue to drive within the State of Hawaii." Since this date has passed, this paragraph is obsolete. This rule removes § 391.69(a).

Miscellaneous

No commenters expressed specific opposition to the proposed technical amendments to § 391.51(b)(2) and § 391.51(g), by which various titles for the position of Regional Director would be replaced by the proper title, "Regional Director of Motor Carriers."

FHWA Response: There are numerous other places within chapter III of title 49 where the position of Regional Director is mentioned by an obsolete title, such as, Regional Director, Motor Carrier Safety; Regional Director, Office of Motor Carrier Safety; Director, Regional Motor Carrier Safety Office; etc. Rather than making technical amendments to § 391.51(b)(2) and § 391.51(g) only, the FHWA has decided to make a nomenclature change to correct all obsolete references to the position of Regional Director in chapter III of title 49 to identify the position by its correct title, Regional Director of Motor Carriers, and to make a slight modification to its definition in § 390.5.

PART 392—DRIVING OF MOTOR VEHICLES

The FHWA proposed to remove several sections of the FMCSRs which were identified as being redundant of State and local regulations and more appropriately regulated by State and local authorities.

Corrective Lenses To Be Worn

Eleven commenters supported and five commenters opposed the removal of § 392.9a, Corrective lenses to be worn. Four of the five opposing commenters were primarily concerned about removing the requirement that a driver who wears contact lenses have a spare lens or set of lenses on his/her person while driving. These commenters wanted to ensure that a driver whose contact lenses become lost or damaged be able to continue to drive with corrected vision.

FHWA Response: The requirements of § 392.9a are duplicative of other sections of the FMCSRs and State regulations. If a driver meets the vision standards only when wearing corrective lenses, § 391.43 requires the medical examiner to check the box, "Qualified only when wearing corrective lenses" on the medical examiner's certificate. Therefore, a driver who meets the vision standards only when wearing corrective lenses is not medically qualified to drive a CMV in interstate commerce when not wearing corrective lenses. A driver who is subject to and does not meet the medical qualification standards is prohibited from driving a CMV in interstate commerce.

Section 392.9a is also duplicative of State driver licensing laws. Most, if not all, States place a restriction on driver's licenses requiring persons who need glasses or contact lenses to wear them while driving.

Other than spare power sources for hearing aids and spare fuses, the FMCSRs do not require extra equipment in any other section. For example, the FMCSRs do not require CMV drivers to carry a spare headlight or other lamp in case a required lamp fails to operate. The carriage of extra equipment, including spare contact lenses, to ensure against possible contingencies is best addressed by company policy.

The removal of § 392.9a does not affect the requirement that a driver comply with the vision standards when operating a CMV in interstate commerce. This rule removes § 392.9a.

Section 392.12 Drawbridges; Stopping of Buses

Section 392.18 Slow Moving Vehicles; Hazard Warning Signal Flashers

Section 392.21 Stopped Vehicles Not To Interfere With Other Traffic

Only one commenter expressed specific opposition to the removal of any of these sections. The Chemical Waste Transportation Institute opposed the removal of § 392.21 on the ground that interstate motor carriers would have to modify their training programs depending upon the jurisdictions in which they travel.

FHWA Response: These sections are duplicative of and more appropriately addressed by State and local regulations. All States and localities require compliance with traffic laws. State and local law enforcement officers are responsible for maintaining proper traffic flow and handling slow moving and stopped vehicles.

A CMV must be operated in accordance with the laws and regulations of the jurisdiction in which it is being operated. Section 392.2 of the FMCSRs emphasizes this requirement. Even if § 392.21 were retained, motor carriers and drivers would still be required to comply with the State and local regulations pertaining to stopped motor vehicles. The removal of § 392.21 would not change this obligation. In addition, the regulatory requirements imposed by Federal, State, and local authorities change over time. Therefore, motor carrier training programs will eventually have to be modified to reflect regulatory changes. This rule removes §§ 392.12, 392.18, and 392.21.

Section 392.30 Lighted Lamps; Moving Vehicles

The Chemical Waste Transportation Institute was the only commenter that expressed specific opposition to the removal of this section. The Institute did so for the same reason it opposed the removal of § 392.21.

FHWA Response: This section is duplicative of State laws and can only be enforced by State and local authorities. The retention of a Federal rule which is redundant of State or local regulations and more appropriately monitored and enforced by these authorities is not justifiable solely because driver training programs may have to be modified.

Section 392.31 Lighted Lamps; Stopped or Parked Vehicles

Twelve commenters supported and three commenters opposed the removal of this section. The Chemical Waste Transportation Institute's objection was based on the same reasoning discussed above. The Advocates for Highway and Auto Safety commented that the removal of this section is premature until the FHWA concludes its conspicuity rulemaking. The ATA argued that this section should be retained to inhibit localities from promulgating and enforcing non-uniform and potentially burdensome regulations.

FHWA Response: Section 392.22, Emergency signals; stopped vehicles, requires hazard warning signal flashers to be activated whenever a motor vehicle is stopped upon the traveled portion or shoulder of a highway until warning devices are placed. Section 392.22(b) specifies how and when warning devices must be placed, both in business or residential districts and on the public highway. The FHWA has determined that § 392.31 is unnecessary in light of the requirements of § 392.22. All of the situations covered by § 392.31 are more thoroughly addressed by § 392.22.

On January 19, 1994, the FHWA published an advance notice of proposed rulemaking (ANPRM) in the **Federal Register** (59 FR 2811) which announced that the agency is considering issuing a proposal to require the use of retroreflective sheeting or reflex reflectors on certain trailers manufactured prior to December 1, 1993, the effective date of the National Highway Traffic Safety Administration's final rule on conspicuity for newly manufactured trailers. This ANPRM did not address the display or lighting of lamps. The requirements of § 392.22 provide sufficient warning to other motor vehicle traffic that a CMV is stopped or parked on the traveled portion or shoulder of a highway. Therefore, the removal of § 392.31 is not premature.

The lighting requirements for stopped or parked vehicles are better monitored and enforced by State and local authorities. Section 392.31 contains a provision that no lamps need be lighted if there is sufficient highway lighting to make persons and vehicles discernible at a distance of 500 feet, unless lighted lamps are required by local regulations. Since § 392.31 is contingent upon local regulations, its removal would not free or encourage localities to promulgate and enforce different lighting requirements for stopped or parked vehicles. This rule removes § 392.31.

Section 392.40 All Accidents

Eleven commenters supported and four commenters opposed the removal of § 392.40, which requires a CMV driver involved in an accident resulting in death, injury, or property damage to: Stop; prevent further accident; assist injured persons; provide driver, motor carrier, and CMV identification information; and report the accident to his/her employer. The Chemical Waste Transportation Institute raised the same training argument discussed above. Pinnacle Transportation Services claimed that the removal of this section would likely lead to a medley of inconsistent State regulations about the responsibilities of a driver involved in an accident. The ATA claimed that the position of a motor carrier in litigation is strengthened if it shows that § 392.40 was complied with rather than a State accident reporting requirement.

FHWA Response: All States already have requirements for a driver of a CMV involved in an accident. Compliance with § 392.40 does not exempt a motor carrier or driver from such State or local regulations, nor does it supplement them. The requirement in paragraph (e) of § 392.40 that drivers report all details of an accident to the motor carrier as

soon as practicable is best handled by company policy rather than by the FMCSRs. The accident reporting requirements for motor carriers which were formerly contained in part 394 of the FMCSRs were removed effective March 4, 1993 (58 FR 6726, February 2, 1993), and with them the need to require CMV drivers to report accidents to their employing motor carriers. This rule removes § 392.40.

Section 392.41 Striking Unattended Vehicle

Twelve commenters supported and three commenters opposed the removal of this section. The Chemical Waste Transportation Institute repeated the same training argument discussed above. The ATA recommended that this section be retained in order to preempt a variety of State regulations which are slightly different.

FHWA Response: As previously stated, compliance with the FMCSRs does not exempt a motor carrier or driver from complying with a similar State or local regulation. The requirements for a driver of a CMV that strikes an unattended motor vehicle upon the highway are appropriately monitored and enforced by State and local authorities. The requirements in § 392.41 are duplicative and cause confusion. This rule removes § 392.41.

Title to Subpart E

The removal of §§ 392.40 and 392.41 eliminates, for the purposes of the FMCSRs, the duties of a driver involved in an accident. Therefore, this rule changes the title to subpart E of part 392 from "Accidents and License Revocation; Duties of Driver" to "License Revocation; Duties of Driver."

Section 392.61 Driving by Unauthorized Person

Ten commenters supported and four commenters opposed the removal of this section. Pinnacle Transportation Services declared that its removal would require thousands of policy manuals to be rewritten. The Advocates for Highway and Auto Safety commented that an action that may lead to an out-of-service violation should continue to be prohibited by the FMCSRs. The ATA commented that the backing of a Federal regulation strengthens the position of motor carrier management in dealing with a driver who permits an unauthorized person to drive the motor carrier's CMV.

FHWA Response: The FMCSRs change over time, sometimes significantly, and policy manuals have to change with them. It is not justifiable to retain § 392.61 merely to avoid having to revise a page in a policy manual. The removal of § 392.61 would not affect any enforcement action taken after the discovery of an unqualified driver during a roadside inspection performed in compliance with the North American Uniform Out-of-Service Criteria. Any person who drives a CMV must meet the qualification standards in part 391 and the CDL standards in part 383. Motor carriers still have the backing of the FMCSRs in prohibiting an unqualified person to drive their CMVs. A Federal prohibition on the use of a qualified driver intrudes in an area which is best handled by company policy or labor-management agreement. This rule removes § 392.61.

Section 392.62 Bus driver; Distraction

No commenter expressed specific opposition to the removal of this section.

FHWA Response: Section 392.62, which prohibits a bus driver from engaging in any unnecessary conversation or other distracting activity, duplicates State and local regulations. This rule removes § 392.62.

Section 392.65 Sleeper Berth; Transfer To or From

No commenter expressed specific opposition to the removal of this section.

FHWA Response: Section 392.65 is obsolete. There are very few truck-tractors currently in use that require entry into the sleeper berth from outside the motor vehicle. This rule removes § 392.65.

Section 392.69 Sleeper Berth, Occupation

Only Pinnacle Transportation Services expressed specific opposition to the removal of this section, on the ground that thousands of policy manuals would have to be rewritten.

FHWA Response: As stated in a previous response, the retention of a section of the FMCSRs is not justifiable merely to avoid the revision of motor carriers' policy manuals. The number of persons occupying a sleeper berth when the vehicle is in motion is best addressed by company policy or labor-management agreement. This rule removes § 392.69.

PART 395—HOURS OF SERVICE OF DRIVERS

The driver requirements of §§ 392.40 and 392.41 relating to accidents are mentioned in paragraph (6) of the definition of *On duty time* in § 395.2. Since §§ 392.40 and 392.41 are being removed, paragraph (6) of the definition of *On duty time* is also being removed.

PART 396—INSPECTION, REPAIR, AND MAINTENANCE

The FHWA proposed to remove the lubrication record required by § 396.3(b)(4).

Lubrication Record

No commenter expressed specific opposition to the removal of this requirement.

FHWA Response: Section 396.3(b)(3) already requires motor carriers to maintain, for vehicles controlled for 30 consecutive days or more, a record of inspection, repairs, and maintenance indicating their date and nature. Since the lubrication record required by § 396.3(b)(4) is a maintenance record, the requirement is redundant. This rule removes § 396.3(b)(4).

Appendix A to Subchapter B

The FHWA proposed to remove appendix A to subchapter B of chapter III, 49 CFR, which includes all published interpretations that were issued by the FHWA before the publication of interpretations on November 23, 1977 (42 FR 60078). The Advocates for Highway and Auto Safety was the only commenter that opposed the removal of this appendix. The Advocates claimed the interpretations in the appendix are still valid to the extent they are not inconsistent with the Regulatory Guidance for the FMCSRs published in the **Federal Register** (58 FR 60734) on November 17, 1993. The Advocates recommended that appendix A become a complete compilation of the FHWA's official interpretations and guidance regarding the FMCSRs.

FHWA Response: Although the interpretations in appendix A, like others issued by the FHWA, remain valid if consistent with the 1993 publication referred to above, many interpretations are outmoded and of little value. The interpretations which were determined by the FHWA to be relevant to current motor carrier operations were included in the 1993 publication. The printing of all previously issued interpretations in an appendix would not be useful because some interpretations depend on factual premises which are not fully explained in the interpretation. The FHWA is presently considering a rulemaking action to codify certain longstanding interpretations which are not based on unique circumstances. This rule removes appendix A since it is obsolete.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

This rule removes obsolete and redundant regulations from the FMCSRs. The FHWA has determined that this regulatory action is not significant under Executive Order 12866 or the regulatory policies and procedures of the DOT. It is anticipated that the economic impact of this regulatory action will be minimal. Therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this regulatory action on small entities. This action would lessen the regulatory burden on small and large entities subject to the FMCSRs by, among other things, removing the recordkeeping requirements associated with the written examination. The FHWA hereby certifies that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of a full Federalism Assessment.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal-Domestic Assistance Program Number 20.217, Motor Carrier Safety. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

This rulemaking action does not contain a collection of information requirement for purposes of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

National Environmental Policy Act

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 and has determined that it would have no effect on the quality of the environment.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 49 CFR Parts 382, 390, 391, 392, 395, and 396

Highway safety, Highways and roads, Motor carriers, and Motor vehicle safety.

Issued on: November 10, 1994.

Rodney E. Slater,

Federal Highway Administrator.

In consideration of the foregoing and under the authority of 42 U.S.C. 4917 and 49 U.S.C. 104, 501 et seq., 521 et seq., 5101 et seq., 5113, 5901 et seq., 31101–31104, 31108, 31131 et seq., 31161, 31301 et seq., 31501 et seq.; and 49 CFR 1.48, the FHWA amends title 49, Code of Federal Regulations, Chapter III, as follows:

CHAPTER III—[AMENDED]

1. Chapter III is amended by substituting the phrase "Regional Director of Motor Carriers" for any of the following phrases for each appearance in the chapter: "Director, Regional Motor Carrier Safety Office of the Bureau of Motor Carrier Safety", "Director, Regional Motor Carrier Safety Offices", "Regional Director, Office of Motor Carriers", "Regional Directors of Motor Carrier Safety", "Regional Director, Motor Carrier Safety", "Regional Director, Office of Motor Carrier Safety", "Directors of Regional Motor Carrier Safety Offices", and "Regional Director".

PART 382—CONTROLLED SUBSTANCES AND ALCOHOL USE AND TESTING

2. The authority citation for part 382 is revised to read as follows:

Authority: 49 U.S.C. 31136, 31301 et seq., 31502; and 49 CFR 1.48.

§ 382.107 [Amended]

3. Section 382.107 is amended by revising the definition for *Safety-sensitive function* to read as follows:

§ 382.107 Definitions.

* * * * *

Safety-sensitive function means any of those on-duty functions set forth in § 395.2 *On duty time*, paragraphs (1) through (6) of this chapter.

* * * * *

PART 390—FEDERAL MOTOR CARRIER SAFETY REGULATIONS; GENERAL

4. The authority citation for part 390 is revised to read as follows:

Authority: 49 U.S.C. 31132, 31136, 31502, and 31504; and 49 CFR 1.48.

5. Section 390.5 is amended by revising the definition for *Regional Director* to read as follows:

§ 390.5 Definitions.

* * * * *

Regional Director of Motor Carriers means the Director of the Office of Motor Carriers, Federal Highway Administration, for a given geographical region of the United States.

* * * * *

PART 391—QUALIFICATIONS OF DRIVERS

6. The authority citation for part 391 is revised to read as follows:

Authority: 49 U.S.C. 504, 31136, and 31502; and 49 CFR 1.48.

§ 391.11 [Amended].

7. Section 391.11 is amended by removing paragraph (b)(11), and redesignating paragraph (b)(12) as paragraph (b)(11).

§§ 391.35 and 391.37 [Removed]

8. The revision to § 391.35(a) published at 59 FR 8752, Feb. 23, 1994, which is to become effective on January 1, 1995, and Sections 391.35 and 391.37 are removed.

§ 391.51 [Amended]

9. Section 391.51 is amended as follows:

a. In paragraph (b)(2), by removing the words "The Regional Federal Highway Administrator's letter" and adding in lieu thereof the words "The letter from the Regional Director of Motor Carriers";

b. In paragraph (c)(3), by adding "and" at the end of paragraph;

c. In paragraph (c)(4), by removing "; and" and adding in lieu thereof a period;

d. By removing paragraph (c)(5); and

e. By removing paragraph (d)(3), and redesignating paragraph (d)(4) as paragraph (d)(3), and by adding the word "and" at the end of paragraph (d)(2).

10. Section 391.61 is revised to read as follows:

§ 391.61 Drivers who were regularly employed before January 1, 1971.

The provisions of § 391.21 (relating to applications for employment), § 391.23

(relating to investigations and inquiries), and § 391.31 (relating to road tests) do not apply to a driver who has been a regularly employed driver (as defined in § 390.5 of this subchapter) of a motor carrier for a continuous period which began before January 1, 1971, as long as he/she continues to be a regularly employed driver of that motor carrier. Such a driver is qualified to drive a motor vehicle if he/she fulfills the requirements of paragraphs (b)(1) through (b)(9) of § 391.11 (relating to qualifications of drivers).

11. Section 391.67 is revised to read as follows:

§ 391.67 Drivers of articulated (combination) farm vehicles.

The following rules in this part do not apply to a farm vehicle driver (as defined in § 390.5) who is 18 years of age or older and who drives an articulated motor vehicle:

(a) Section 391.11(b)(1), (b)(8), (b)(10), and (b)(11) (relating to driver qualifications in general);

(b) Subpart C (relating to disclosure of, investigation into, and inquiries about the background, character, and driving record of, drivers);

(c) Subpart D (relating to road tests);

(d) So much of §§ 391.41 and 391.45 as require a driver to be medically examined and to have a medical examiner's certificate on his person before January 1, 1973; and

(e) Subpart F (relating to maintenance of files and records).

12. Section 391.68 is revised to read as follows:

§ 391.68 Private motor carrier of passengers (nonbusiness).

(a) The following rules in this part do not apply to a private motor carrier of passengers (nonbusiness) and their drivers:

(1) Section 391.11(b)(8), (b)(10), (b)(11), and (b)(12), (relating to driver qualifications in general).

(2) Subpart C (relating to disclosure of, investigation into, and inquiries about the background, character, and driving record of, drivers).

(3) Subpart D (relating to road tests).

(4) So much of §§ 391.41 and 391.45 as require a driver to be medically examined and to have a medical examiner's certificate on his/her person.

(5) Subpart F (relating to maintenance of files and records).

(6) Subpart H (relating to controlled substances testing).

(b) The following rules in this part do not apply to a private motor carrier of passengers (business) driver: Subpart D (relating to road tests).

13. Section 391.69 is revised to read as follows:

§ 391.69 Drivers operating in Hawaii.

The provisions of § 391.21 (relating to application for employment), § 391.23 (relating to investigations and inquiries), and § 391.31 (relating to road tests) do not apply to a driver who has been a regularly employed driver (as defined in § 390.5 of this subchapter) of a motor carrier operating in the State of Hawaii for a continuous period which began before April 1, 1975, as long as he/she continues to be a regularly employed driver of that motor carrier. Such a driver is qualified to drive a motor vehicle if he/she fulfills the requirements of paragraphs (b)(1) through (b)(9) of § 391.11 (relating to qualifications of drivers).

§ 391.71 [Amended]

14. In § 391.71, paragraph (a) is amended by removing the words "and § 391.35 (relating to written examination)" and adding the word "and" before the reference to "§ 391.31."

15. Section 391.73 is revised to read as follows:

§ 391.73 Private motor carrier of passengers (business).

The provisions of § 391.21 (relating to applications for employment), § 391.23 (relating to investigations and inquiries), and § 391.31 (relating to road tests) do not apply to a driver who has been a regularly employed driver (as defined in § 390.5 of this subchapter) of a private motor carrier of passengers (business) as of July 1, 1994, so long as the driver continues to be a regularly employed driver of that motor carrier. Such a driver is qualified to drive a motor vehicle if that driver fulfills the requirements of paragraphs (b)(1) through (b)(9) of § 391.11 (relating to qualifications of drivers).

PART 392—DRIVING OF MOTOR VEHICLES

16. The authority citation for part 392 is revised to read as follows:

Authority: 49 U.S.C. 31136 and 31502; and 49 CFR 1.48.

§§ 392.9a, 392.12, 392.18, 392.21, 392.30, 392.31, 392.32, 392.40, 392.41, 392.61, 392.62, 392.65, and 392.69 [Removed and Reserved]

17. Sections 392.9a, 392.12, 392.18, 392.21, 392.30, 392.31, 392.32, 392.40, 392.41, 392.61, 392.62, 392.65, and 392.69 are removed and reserved.

18. The heading of subpart E is revised to read, "Subpart E—License Revocation; Duties of Driver".

PART 395—HOURS OF SERVICE OF DRIVERS

19. The authority citation for part 395 is revised to read as follows:

Authority: 49 U.S.C. 31136 and 31502; and 49 CFR 1.48.

§ 395.2 [Amended]

20. The definition of *On duty time* is amended by removing paragraph (6) and redesignating paragraphs (7) through (9) as paragraphs (6) through (8), respectively.

PART 396—INSPECTION, REPAIR, AND MAINTENANCE

21. The authority citation for part 396 is revised to read as follows:

Authority: 49 U.S.C. 31136 and 31502; and 49 CFR 1.48.

§ 396.3 [Amended]

22. Section 396.3 is amended by removing paragraph (b)(4) and redesignating paragraph (b)(5) as paragraph (b)(4), and by adding the word "and" at the end of paragraph (b)(3).

Appendices A and C to Subchapter B [Removed and Reserved]

23. In chapter III, subchapter B, appendices A and C are removed and reserved.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018-AB97

Endangered and Threatened Wildlife and Plants; Appalachian Elktoe Determined To Be an Endangered Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service) determines the Appalachian elktoe (*Alasmidonta raveneliana*) to be an endangered species under the Endangered Species Act of 1973, as amended (Act). The Appalachian elktoe is endemic to the upper Tennessee River system in the mountains of western North Carolina and eastern Tennessee. It was once fairly widely distributed in western North Carolina, but it has been

eliminated from the majority of its historic range and is now found only in short reaches of the Little Tennessee River, Nolichucky River, Toe River, and Cane River. In Tennessee, the species is known only from its present distribution in the Nolichucky River. The species' range has been seriously reduced by impoundments and the general deterioration of habitat and water quality resulting from siltation and other pollutants contributed by poor land use practices and toxic discharges. Due to the species' limited distribution, any factors that adversely modify habitat or water quality in the stream reaches it now inhabits could further threaten the species. This final rule implements the Act's protection and recovery provisions for the Appalachian elktoe.

EFFECTIVE DATE: December 23, 1994.

ADDRESSES: The complete file for this rule is available for inspection, by appointment, during normal business hours at U.S. Fish and Wildlife Service, 330 Ridgefield Court, Asheville, North Carolina 28806.

FOR FURTHER INFORMATION CONTACT: Mr. John Fridell at the above address (704/665–1195, Ext. 225).

SUPPLEMENTARY INFORMATION:

Background

The Appalachian elktoe (*Alasmidonta raveneliana*) (Lea, 1834) is a freshwater mussel with a thin, but not fragile, kidney-shaped shell, reaching up to about 3.2 inches in length, 1.4 inches in height, and 1 inch in width (Clarke 1981). Juveniles generally have a yellowish-brown periostracum (outer shell surface) while the periostracum of the adults is usually dark brown in color. Although rays are prominent on some shells, particularly in the posterior portion of the shell, many individuals have only obscure greenish rays. The shell nacre (inside shell surface) is shiny, often white to bluish-white, changing to a salmon, pinkish, or brownish color in the central and beak cavity portions of the shell; some specimens may be marked with irregular brownish blotches (adapted from Clarke 1981). A detailed description of the species' shell, with illustrations, is contained in Clarke (1981). Soft parts are discussed in Ortmann (1921).

Because of its rarity, little is known about the autecology of the Appalachian elktoe. The species has been reported from relatively shallow, medium-sized creeks and rivers with cool, moderate- to fast-flowing water. It has been observed in gravelly substrates often mixed with cobble and boulders, in cracks in bedrock (Gordon 1991), and occasionally in relatively silt-free, coarse, sandy substrates (J. Alderman, North Carolina Wildlife Resources Commission, personal communication, 1992; personal observations, 1989 and 1991). Like other freshwater mussels, the Appalachian elktoe feeds by filtering food particles from the water column. The specific food habits of the species are unknown, but other freshwater mussels have been documented to feed on detritus, diatoms, phytoplankton, and zooplankton (Churchill and Lewis 1924). The reproductive cycle of the Appalachian elktoe is similar to that of other native freshwater mussels. Males release sperm into the water column; the sperm are then taken in by the females through their siphons during feeding and respiration. The females retain the fertilized eggs in their gills until the larvae (glochidia) fully develop. The mussel glochidia are released into the water, and within a few days they must attach to the appropriate species of fish, which they then parasitize for a short time while they develop into juvenile mussels. They then detach from their "fish host" and sink to the stream bottom where they continue to develop, provided they land in a suitable substrate with the correct water conditions. Recent studies funded by the U.S. Forest Service and conducted by personnel with the Tennessee Technological University at Cookeville, Tennessee, have identified the banded sculpin (*Cottus carolinae*) as a host species for glochidia of the Appalachian elktoe (M. Gordon, Tennessee Technological University, personal communication, 1993).

The mussel's life span, and many other aspects of its life history, are unknown.

The Appalachian elktoe is known to be endemic to the upper Tennessee River system in western North Carolina and eastern Tennessee. Historical records for the species in North Carolina exist for the Little Tennessee River system (Talula Creek, Graham County) and the French Broad River system, including the Nolichucky River (county unknown); the Little River (Transylvania County), the Swannanoa River (county unknown), the Pigeon River (Haywood County), and the main stem of the French Broad River (Buncombe County and an unknown county) (Clarke 1981). An additional historical record of the Appalachian elktoe in the North Fork Holston River, Tennessee (S.S. Haldeman collection) is believed to represent a mislabeled locality (Gordon 1991).

From 1986 through the spring of 1992, biologists with the Service, the Tennessee Valley Authority, the North Carolina Wildlife Resources Commission, and the Tennessee Technological University conducted surveys in both historic and potential habitat of the species. Surveys of the French Broad River and its tributaries in Transylvania, Henderson, Haywood, Buncombe, and Madison Counties, North Carolina, failed to locate any specimens of the Appalachian elktoe (R. Biggins, U.S. Fish and Wildlife Service, personal communications, 1989 and 1991; Alderman, North Carolina Wildlife Resources Commission, personal communication, 1990; M. Gordon, Tennessee Technological University, personal communications, 1991 and 1992; personal observations, 1986 through 1991). The species has also been extirpated from Talula Creek in the Little Tennessee River system (personal observations, 1987 and 1992) and could not be found in any of the other major tributaries to the Little Tennessee River (Gordon, personal communication, 1991; S. Ahlstedt, Tennessee Valley Authority, personal communication, 1992). If the historic record for the species in the North Fork Holston River in Tennessee was a good record, then the species has been eliminated from this river as well. Only two populations of the species are known to survive. One population, discovered in 1987 by Tennessee Valley Authority biologists (Steven Ahlstedt and Charles Saylor), exists in the main stem of the Little Tennessee River in Swain and Macon Counties, North Carolina (Tennessee Valley Authority 1987; J. Widlak, U.S. Fish and Wildlife Service, personal communication, 1988; Biggins 1990; Gordon 1991; personal observations, 1988, 1991, 1992, 1993). The second population occurs in the Nolichucky River system. This population is restricted to scattered locations along a short reach of the Toe River in Yancey and Mitchell Counties in North Carolina (personal observations, 1991 and 1992) and the main stem of the Nolichucky River, Yancey and Mitchell Counties, North Carolina (Alderman, personal communication, 1991; personal observation, 1992, 1993), extending downriver into Unicoi County, Tennessee (personal observation, 1992). A single specimen of the Appalachian elktoe was also found in the Cane River in Yancey County, North Carolina (C. McGrath, North Carolina Wildlife Resources Commission, personal communication, 1992).

Habitat and water quality degradation/alteration resulting from impoundments; stream channelization;

dredging; industrial and sewage effluent; and the runoff of silt and other pollutants from poorly implemented mining, construction/development, agricultural, and past logging activities are believed to be the primary factors resulting in the elimination of the species from the majority of its historic range. Many of these factors threaten the only two remaining populations of the species.

Previous Federal Action

The Appalachian elktoe was recognized by the Service in the May 22, 1984, Federal Register (49 FR 21664) and again in the January 6, 1989, Federal Register (54 FR 554) as a species being reviewed for potential addition to the Federal List of Endangered and Threatened Wildlife and Plants. This mussel was designated as a category 2 candidate for Federal listing on these candidate lists. Category 2 represents those species for which the Service has some information indicating that the taxa may be under threat, but sufficient information is lacking to prepare a proposed rule. Since that time, both historic and potential habitat of the species has been surveyed. Only two populations of the Appalachian elktoe are known to survive, and both of these populations are threatened by many of the same factors that are believed to have resulted in the extirpation of the species elsewhere within its historic range. Accordingly, on June 10, 1992, the Service designated the Appalachian elktoe as a category 1 candidate. Category 1 represents those species for which the Service has enough substantial information on biological vulnerability and threats to support proposals to list them as endangered or threatened species. The Service has met and been in contact with various Federal and State agency personnel and private individuals knowledgeable about the species, concerning the species' status and the need for protection provided by the Act. On April 20, 1992, and again on August 21, 1992, the Service notified appropriate Federal, State, and local government agencies in writing that a status review was being conducted and that the species might be proposed for Federal listing. A total of six written comments were received on these two notices. The North Carolina Wildlife Resources Commission (two written comments), the North Carolina Natural Heritage Program (two written comments), and an interested biologist expressed their support for the species' being proposed for protection under the Act; the U.S. Soil Conservation Service stated that they did not have any additional information on this species. No negative comments were received.

On September 3, 1993, the Service published in the Federal Register (58 FR 46940) a proposal to list the Appalachian elktoe as an endangered species. That proposal provided information on the species' biology, status, and threats to its continued existence.

Summary of Comments and Recommendations

In the September 3, 1993, proposed rule, the January 21, 1994, notice of public hearing and reopening of the comment period (59 FR 12353), the February 8, 1994, public hearing, and through associated notifications, comments or suggestions concerning the proposed rule were solicited from the public, concerned governmental agencies, the scientific community, industry, or any other interested party. Appropriate Federal and State agencies, county governments, scientific organizations, and interested parties were contacted by letters dated September 14, 1993, and January 27, 1994, and were requested to comment. A legal notice, which invited general public comment, was published in the following newspapers: "The Erwin Record," Erwin, Tennessee, September 22, 1993; the "Mitchell News Journal," Spruce Pine, North Carolina, September 22, 1993; the "Yancey Journal," Burnsville, North Carolina, September 22, 1993; the "Smoky Mountain Times," Bryson City, North Carolina, September 23, 1993; and the "Franklin Press," Franklin, North Carolina, September 24, 1993.

In response to three formal requests, a public hearing on the proposal to list the Appalachian elktoe as an endangered species was held on February 8, 1994, at the Mitchell High School, Bakersville, North Carolina. A legal notice announcing the public hearing and reopening of the comment period was published in the newspapers listed above.

All written comments and oral statements presented at the public hearing and those received during the comment periods are covered in the following discussion.

Four written responses to the proposed rule were received during the initial comment period. One of these was from a State agency, and the others were from the mining industry in Mitchell County, North Carolina. The State of Tennessee, Department of Environment and Conservation expressed support for the listing of the Appalachian elktoe as endangered, and stated that their Heritage Program records concurred with the information presented in the proposed rule. The Unimin Corporation, Feldspar Corporation, and K–T Feldspar Corporation expressed concern about the potential listing and requested that a public hearing on the Service's proposal be held.

Nineteen verbal statements were made at the public hearing. Fifteen respondents (a representative of Congressman Taylor's office, the Mitchell County Board of Commissioners, the Mayor of the Town of Spruce Pine, the Mitchell County Soil and Water Conservation District, the Mitchell County Economic Development Commission, the Mitchell County Christmas Tree Growers Association, representatives of three mining companies, and six individuals) expressed opposition to the listing of the Appalachian elktoe. Four respondents (representatives of two businesses, a civic group, and a representative for 31 children in east Tennessee) supported the listing. Ten written comments were received at the public hearing, nine of which were copies of verbal statements given. A written statement was also received from Congressman Cass Ballenger. Congressman Ballenger expressed his interest in the matter and stated that he had sent a representative of his office to the hearing.

Forty additional written comments were received during the comment period extension (thirty-one letters were received from children in Chucky, Tennessee, but are counted in this total as one comment from the children in east Tennessee). Nine of these respondents (Congressman Charles Taylor, Congressmen Cass Ballenger, The K–T Feldspar Corporation, The Unimin Corporation, and five individuals) opposed the listing; thirty respondents (members of the League of Women Voters, Save our Rivers, a registered forester, and 26 other respondents) supported the listing; one respondent (Nantahala Power and Light Company) expressed neither support for nor opposition to the listing.

Following is a summary of comments, concerns, and questions (referred to as "Issues" for the purpose of this summary) expressed orally at the public hearing or in writing during the reopened comment period. Issues of similar content have been grouped together. These issues and the Service's response to each are presented below.

Issue 1: Congressman Taylor, Congressman Ballenger, the Mitchell County Soil and Water Conservation District, the Mitchell County Economic Development Commission, the Mayor of

the town of Spruce Pine, three mining companies in Mitchell County, North Carolina and several other respondents questioned the need for the Service to list the Appalachian elktoe because the species is already listed by the State of North Carolina and is protected under North Carolina's environmental laws.

Service Response: While the species is currently listed by the State of North Carolina as an endangered species, State regulations pertaining to State listed fish and wildlife, including freshwater mussels, prohibit only the take of such species. These regulations do not specifically protect State endangered and threatened species from other threats. Federal listing will provide additional protection for the Appalachian elktoe throughout its range by requiring Federal agencies, under Section 7 of the Act, to insure that their actions are not likely to jeopardize the continued existence of the Appalachian elktoe. Federal actions subject to Section 7 of the Act that could occur and impact the species include, but are not limited to, the carrying out or issuance of permits for road and bridge construction, forestry activities on National Forest lands, reservoir construction, river channel maintenance or other dredging activities, stream and wetland alterations, and potentially harmful wastewater discharges in relatively close proximity to the occupied habitat of the species. If the species was not listed, there would be no legal requirement for Federal agencies under the Act, involved in these types of activities to give the species any special consideration in their project planning or authorization. In the majority of the cases involving listed mussels (particularly the majority of highway and bridge projects, forestry activities, and other land disturbance projects), only minor project changes or modifications are necessary to protect the species (i.e., a commitment for the implementation and maintenance of adequate erosion and sedimentation control measures). These measures benefit not only the listed species involved but also the entire river ecosystem and the river's aesthetic and recreational values.

Further, Federal listing of the Appalachian elktoe will help to make the species, and areas where the species still exists, a high priority for potential Federal (and in some cases State and private) funding sources to help implement recovery actions for the species and corrective measures at problem sites within the watersheds where the species exists.

Issue 2: The Mayor of Spruce Pine questioned whether the Service felt the State of North Carolina is not adequately protecting the Appalachian elktoe.

Service Response: Protection and recovery of the Appalachian elktoe cannot be achieved by the efforts of the States of North Carolina and Tennessee alone or by efforts of the Service and other Federal agencies alone. Protection and recovery of this species requires a cooperative effort and will depend on assistance and support of the local landowners, communities, private industries, businesses, and interest groups, as well as the local, State, and Federal agencies.

Issue 3: Congressman Taylor, Congressman Ballenger, the Mayor of the Town of Spruce Pine, one mining company, and two individuals questioned the factors cited by the Service as having contributed to the decline of the Appalachian elktoe, in particular pollution from industrial and municipal sources and siltation.

Service Response: Siltation has been documented to adversely affect native freshwater mussels both directly and indirectly. Siltation degrades water and substrate quality limiting available habitat for freshwater mussels (and their fish hosts), irritates and clogs the gills of filter-feeding mussels resulting in reduced feeding and respiration, smothers mussels if sufficient accumulation occurs, and increases the potential exposure of the mussels to other pollutants (Ellis 1936, Marking and Bills 1979, Kat 1982). Ellis (1936) found that less than one inch of sediment deposition caused high mortality in most mussel species. Sediment accumulations which are less than lethal to adults may adversely affect or prevent recruitment of juvenile mussels into the population.

The Appalachian elktoe has not been found in the Nolichucky River system in substrates with accumulations of silt and shifting sand; the species is restricted to small, scattered pockets of stable, relatively clean, gravelly substrates. The same is true of the population surviving in the Little Tennessee River.

Mussels are also known to be sensitive to numerous other pollutants, including but not limited to a wide variety of heavy metals, high concentrations of nutrients, and chlorine (Havlik and Marking 1987)—pollutants commonly found in many domestic and industrial effluents. In the early 1900's Ortmann (1909) noted that unionids (mussels) are the most reliable indicator of stream pollution. Keller and Zam (1991) concluded that mussels were more sensitive to metals than commonly tested fish and aquatic insects. The life cycle of native mussels makes the reproductive stages especially vulnerable to pollutants (Ingram 1957, Stein 1971, Fuller 1974, Gardner *et al* 1976). The toxicity of chlorinated sewage effluents to aquatic life is well documented (Brungs 1976, Tsai 1975, Bellanca and Bailey 1977, U.S. Environmental Protection Agency 1985, Goudreau *et al.* 1988), and mussel glochidia (larvae) rank among the most sensitive invertebrates in their tolerance to toxicants present in sewage effluents (Goudreau *et al.* 1988).

The evidence available demonstrates that habitat deterioration (resulting from sedimentation and pollution from numerous point sources), when combined with the effects of other factors (including non-point source pollution, habitat destruction/alteration resulting from impoundments and channelization projects, etc.), has played a significant role in the decline of the Appalachian elktoe. The Service believes this is particularly true of the extirpation of the species from the Pigeon, Swannanoa, and French Broad Rivers. These factors (primarily sedimentation) likely also contributed to the extirpation of the species from the Little River and Talula Creek. Habitat loss and alteration resulting from impoundments, channel modification projects, and (in the case of Talula Creek) excavation activities within the creek channel are believed to have had a severe adverse effect on the species.

Issue 4: One mining company and one individual asked whether predation posed a threat to the Appalachian elktoe. One of these respondents inquired about the effects of predation by brown trout, "muskie" (muskellunge), and otter; the other inquired concerning the effects of muskrat predation.

Service Response: Shells of the Appalachian elktoe are often found in muskrat middens along the reach of the Little Tennessee River where the species still exists and occasionally in middens along the Nolichucky River. The species also is presumably consumed by other mammals, such as raccoons, mink, and otter. Plankton feeding fish (including hatchling trout and muskellunge) likely occasionally feed on the sperm and glochidia (which are expelled by freshwater mussels directly into the water column), and bottom feeding fish may occasionally feed on mussels, particularly juvenile mussels. However, larger trout and muskellunge feed primarily on insects, crustaceans, amphibians and other fish (mobile aquatic organisms).

While predation is not thought to be a significant threat to a healthy mussel population, it could, as suggested by

Neves and Odum (1989), limit the recovery of endangered mussel species or contribute to the local extirpation of mussel populations already reduced by other factors (see "Summary of Factors Affecting the Species," Part C. *Disease or Predation*, below).

Issue 5: One of the mining companies inquired concerning whether disease posed a threat to freshwater mussels.

Service Response: The Service does not currently have any information to indicate whether disease is a significant threat to freshwater mussels. Since 1982, biologists and commercial mussel fishermen have reported occasional and localized, though extensive, mussel die-offs in rivers and lakes throughout the United States. Pesticides have been implicated as the cause of one of the die-offs that occurred in North Carolina, but the cause(s) of many of these die-offs is unknown and disease has been suggested as a possible factor. (See "Summary of Factors Affecting the Species, factor C. *Disease or Predation*, below)

Issue 6: One of the mining companies inquired about the effect high or low water levels or extreme temperature changes have on the mussel (Appalachian elktoe).

Service Response: Normal water and temperature fluctuations are not believed to have any significant adverse effect on the Appalachian elktoe. However, significant changes in water levels and/or temperature, especially rapid changes, do pose a threat.

The Appalachian elktoe is found in cool, (it has not been recorded from extremely cold or warm waters) moderate to fast-flowing water over stable, relatively silt-free rocky (gravel, cobble, boulder, etc.) substrates (see "Background" section above). Such suitable substrates are generally found in areas where the water current is swift enough to help keep silt and other sediments from accumulating. Lessening these flows increases the potential for siltation of the substrate. Also, these areas are often located in relatively shallow water. Because mussels are basically sedentary, de-watering of these areas traps the mussels and subjects them to heat or cold stress (depending on the time of year), desiccation, and increased predation. Low water or drastic increases in water levels within the river can result in temperature and chemical changes within the water, thus adversely affecting the Appalachian elktoe. Rapid increases in water levels can result in increased scouring and erosion of streambanks and river channel resulting in increased sedimentation of the river.

Issue 7: Nantahala Power and Light Company asked whether surveys had been conducted to determine the species distribution, and one individual suggested the species may occur in other areas.

Service Response: From 1986 through the spring of 1992, biologists with the Service, the North Carolina Wildlife Resources Commission, the Tennessee Valley Authority, and the Tennessee Technological University surveyed both historic and potential habitat of the species (see "Background" section above). Based on the results of these surveys, the Service concludes that it is not likely that additional populations of the Appalachian will be discovered outside of the present known range.

Issue 8: One respondent for the mining industry suggested that the surveys conducted for the species may have been in the wrong habitat type.

Service Response: The surveys that were conducted included the use of scuba and snorkeling equipment, view buckets (glass bottom buckets), and collection of shell middens (accumulations of shells from mussels fed upon by muskrats). Surveys were conducted in deep and shallow water, riffles, shoals, pools, and runs. The species was observed in stable, relatively silt-free gravelly substrates often mixed with cobble and boulders, and in cracks in bedrock (see "Background" section above). On three occasions single individuals were found in relatively clean, coarse sandy substrates. Water currents in the areas where the species was most often observed was moderate to swift. The swift currents helped to keep the substrate flushed of sediments. Deeper and slacker water habitats generally contained accumulations of unstable silt, sand, and other sediments (particularly in the case of the Nolichucky River system), which is believed to help explain the species' absence from these areas.

Issue 9: Several respondents provided information concerning the efforts that have been undertaken by the town of Spruce Pine, the industries in the Spruce Pine area, the local landowners, and others in the Mitchell County area to improve the quality of the North Toe, Toe, and Nolichucky Rivers. Many of these respondents state that because of these efforts, Federal listing of the Appalachian elktoe is not necessary.

Service Response: The Service recognizes that many of the industries, landowners, developers, builders, etc., in these watersheds are implementing measures for controlling the runoff of sediments and other pollutants into the river and its tributaries and commends those actions. The Service also recognizes that these efforts have resulted in improvements in the condition of some areas of the upper Nolichucky River system in recent years. However, while there have been improvements, there are still activities occurring within the watershed that continue to adversely affect the quality of the Toe, Cane, and Nolichucky Rivers, and there are other activities proposed that have the potential to affect these rivers.

The Service believes that the Appalachian elktoe meets the definition of endangered and warrants the protection of the Act. In making this determination the Service has to look at what has happened or is happening to the species throughout the species' range, and what threats there are to the species throughout its range. The Service cannot look at just one area, nor can it look at the threats from just one or a few sources. The Service believes there are numerous ongoing and planned activities, as well as natural threats, in both river systems where the species still survives (see "Summary of Factors Affecting the Species" below) that have the potential to adversely affect the surviving populations.

Issue 10: One representative of the mining industry suggested a cooperative effort (reintroduction of the species into tributaries of the Toe and Nolichucky Rivers) among the Service and the local mining industry might be used to protect the Appalachian elktoe without listing the species.

Service Response: Recovery of the Appalachian elktoe cannot be achieved without reestablishment of the species throughout a significant portion of its historic range. Because the majority of the areas from which the species has been eliminated are isolated from existing populations, natural reestablishment of these areas by the species is impossible and will require human assistance. However, before reintroduction activities can be carried out with confidence that such reintroductions can be successful, additional research is necessary to determine the range of environmental requirements of the species. Artificial propagation of the species may be necessary in order to obtain sufficient numbers of the species for the successful reintroductions—the existing populations, especially the Nolichucky river population, currently appear too small to support removals for reintroductions. Several agencies and institutes are conducting research on artificial propagation and relocation of freshwater mussels, though efforts to date have met with only limited

success. Much more work is needed to perfect these techniques before they can be applied to endangered mussels. Recovery of decimated populations of native freshwater mussels through reintroductions will be an extremely slow and difficult process and will require long-term commitment of funds and effort to carry out and monitor.

Issue 11: Congressman Taylor and Congressman Ballenger, the Mitchell County Board of Commissioners, the Mitchell County Economic Development Commission, the Mayor of the Town of Spruce Pine, and several other respondents expressed economic concerns associated with Federal listing of the Appalachian elktoe.

Service Response: Under section 4(b)(1)(A) of the Act, a listing determination must be based solely on the best scientific and commercial data available concerning the status of a species. The legislative history of this provision clearly states the intent of Congress to ensure that listing decisions are "based solely on biological criteria and to prevent non-biological considerations from affecting such decisions" H.R. Rep. No. 97–835, 97th Cong. 2nd Sess. 19 (1982). As further stated in the legislative history, "economic considerations have no relevance to determinations regarding the status of the species". The Service is prohibited by law from withholding a listing based on concerns regarding economic impact.

While the Service cannot consider economic concerns in determining whether a species is endangered or threatened, other provisions of the Act do allow for the consideration of the potential economic effects of actions or determinations made pursuant to the Act. For instance, in developing a biological opinion under Section 7 of the Act, the Service develops (through consultation with the lead Federal agency and the applicant, if there is one) "reasonable and prudent alternatives" for actions that are determined to be likely to jeopardize the continued existence of a federally listed species, and "reasonable and prudent measures" for actions that are likely to result in incidental take of a federally listed species. In order to be "reasonable and prudent" these alternatives/measures must be technically and economically feasible. If it was determined that a proposed action was likely to jeopardize the continued existence of a federally listed species and there were no reasonable and prudent alternatives to avoid jeopardy, the Act provides a mechanism for the action to be elevated to a cabinet-level Endangered Species Committee for review. If, through this review, it is determined that the benefits of the proposed action to the public outweigh the potential extinction of the species, an exemption from the provisions of the Act can be granted for the project.

The Service is well aware of the economic importance of the Nolichucky River system to Mitchell County. The Service sees no reason why conservation of the Appalachian elktoe cannot be integrated with existing industrial and domestic uses of the river and its tributaries.

Issue 12: Congressman Taylor and Congressman Ballenger, the Mitchell County Board of Commissioners, the Mitchell County Economic Development Commission, the Mayor of the town of Spruce Pine, and several individuals expressed concerns about potential effects to wastewater discharges (in particular discharges from the Town of Spruce Pine and from mining industry in Mitchell County) associated with Federal regulations resulting from listing of the Appalachian elktoe.

Service Response: Section 9 of the Act sets forth a series of general prohibitions and exceptions that apply to all endangered wildlife. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, or collect; or to attempt any of these), import or export, ship in interstate commerce in the course of commercial activity, or sell or offer for sale in interstate or foreign commerce any listed species. It also is illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to agents of the Service and State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving endangered wildlife species under certain circumstances. Regulations governing permits are at 50 CFR 17.22 and 17.23. Such permits are available for scientific purposes to enhance the propagation or survival of the species and/or for incidental take in connection with otherwise lawful activities.

The Service is not aware of any information currently available that indicates existing discharges associated with mining industry in Mitchell County, North Carolina, or the town of Spruce Pine are either adversely affecting the Appalachian elktoe or resulting in a "take" of the species where it presently exists in the Nolichucky River system. Therefore, the Service does not believe regulations under Section 9 of the Act will have any effect on the mining industry or on the town of Spruce Pine into the foreseeable future.

Section 7 of the Act places a requirement on Federal agencies to evaluate their actions (projects that they authorize, fund, or carry out) with respect to any species that is listed as endangered or threatened, and to insure that their actions are not likely to jeopardize the continued existence of a listed species (see Available Conservation Measures below). The requirements under Section 7 of the Act apply only to Federal agencies and therefore would affect only those actions and activities that have Federal involvement (i.e., projects that utilize Federal funding, require Federal permits or authorization, or are carried out by a Federal agency). The Service's role under Section 7 of the Act is to assist other Federal agencies in meeting their obligations with respect to endangered and threatened species.

While National Pollution Discharge Elimination System (NPDES) permits are issued by the North Carolina Department of Environmental Management (NCDEM), the U.S. Environmental Protection Agency (EPA) does have overview authority of the State's NPDES permit program. Therefore, EPA would be required to satisfy its obligations under Section 7 of the Act if it were determined that permit renewal or potential permitting of a new or expanded discharge associated with the mining industry or the town of Spruce Pine was likely to affect the Appalachian elktoe.

The Service cannot say whether or not new or expanded discharges into the Nolichucky River system will be affected by the listing of the Appalachian elktoe without specific information concerning those discharges. Further, under Section 7 of the Act, it is the lead Federal agency, in this case the EPA, that determines whether there is a potential for discharges to affect federally listed species. However, as stated previously, based on the best scientific and commercial information currently available to the Service, the existing permitted discharges do not appear to be adversely affecting existing locations of the Appalachian elktoe.

Expansion of existing discharges would not likely be affected by the listing of the Appalachian elktoe unless: (1) the location of a discharge is moved significantly further downstream to a point where it would be more likely to adversely affect the Appalachian elktoe, (2) the State proposes to grant a variance that would allow a discharge, or

discharges, to exceed current water quality standards for the river, and/or (3) new information becomes available that indicates that the existing discharges or expansion of these discharges are likely having an adverse effect (individually or cumulatively) on the Appalachian elktoe.

In regard to the proposed expansion of the Spruce Pine wastewater treatment plant, in view of the documented toxicity of chlorine to freshwater organisms, the Service will likely request that dechlorination of the effluent and standby power to sustain dechlorination in the event of a power failure be made part of the permit. However, based on conversations with the personnel with the Asheville Regional Office of the NCDEM, this will be a primary recommendation from their office as well.

Also, new or expanding facilities are required to evaluate alternatives to proposed sites of discharge, including nondischarge alternatives, as required under Titles 15A NCAC 2B.201 (c)(1) and 2H.105 (c)(2) of the State's Water Quality Classification and Standards Rules. An environmental assessment is also required of applicants proposing any new discharges of industrial process or domestic wastewater in excess of 500,000 gallons per day. These requirements apply to all such facilities without regard to the presence or absence of endangered species.

Any substantial indications of water quality impairment evidenced by in stream biological monitoring, including the status of downstream threatened or endangered species, may trigger a review of potential causes of water quality degradation upstream.

If the EPA were to determine that a NPDES permit associated with one of the mining companies in Mitchell County was likely to affect the Appalachian elktoe, it has been the experience of the Service that nearly all Section 7 consultations have been resolved so that the species has been protected and the project objectives have been met.

Issue 13: Two respondents expressed concern about the effect the listing would have on current farming practices.

Service Response: The Service encourages the use of best management practices (e.g., buffer strips along water courses, reductions of pesticide applications, soil conservation practices that help control soil loss and siltation, etc.). The Service and other Federal agencies do have programs to assist farmers and other landowners in implementing measures for habitat restoration and improvement. For instance, the Service's Partners for Wildlife Program has the potential to provide funding to interested and willing landowners to help restore degraded areas, fence livestock out of streams and provide alternative livestock water sources, plant filter strips, etc.—measures that many landowners may not otherwise be able to afford.

Issue 14: The Mitchell County Economic Development Commission asked whether listing the Appalachian elktoe would lead to the potential for the Toe River becoming a "resource water".

Response: The North Carolina Division of Environmental Management (NCDEM) is responsible for classifying waters within the State of North Carolina. If the respondent is referring to "Outstanding Resource Water" designation, the State of North Carolina requires that waters eligible for this designation have excellent water quality and have at least one of five values or uses (one of which is that the waters are of special ecological or scientific significance such as habitat for rare or endangered species) that qualifies the water body as having an outstanding resource value. Because the Appalachian elktoe is already listed by the State of North Carolina as endangered, the Toe River, or at least a portion of the Toe River, already meets the second requirement. However, because the Toe River does not currently maintain excellent water quality it does not meet the first requirement and therefore is not eligible.

If the Respondent is referring to "High Quality Water" designation, the State of North Carolina's criteria for this designation does not recognize the Federal status of species. Therefore, Federal listing of the Appalachian elktoe does not effect the Toe River's eligibility, or ineligibility, for this designation.

Issue 15: The Mitchell County Economic Development Commission, one mining company, and two individuals asked whether the fish host for the Appalachian elktoe mussel has been identified and what its numbers are in the Nolichucky River.

Service Response: Recent studies funded by the U.S. Forest Service and conducted by personnel with the Tennessee Technological University at Cookeville, Tennessee, have identified the banded sculpin (*Cottus carolinae*) as a host species for glochidia of the Appalachian elktoe (M. Gordon, Tennessee Technological University, personal communication, 1993). It is possible that other fish species may also serve as host to Appalachian elktoe glochidia. Because the banded sculpin is currently widely distributed and appears to be fairly common, specific studies have not been conducted to determine what the species' population levels are in the Nolichucky and Little Tennessee river systems. Like the Appalachian elktoe, the banded sculpin is generally found in riffle areas and appears to be sensitive to sedimentation and water pollution. Reductions of the population levels of the banded sculpin may be a factor contributing to the limited distribution and numbers of the Appalachian elktoe. However, evidence of reproduction of the Appalachian elktoe in recent years, albeit limited in the Nolichucky River population of the species, has been observed in both surviving populations of the species (personal observation 1992), so a fish host is present. In identifying and attempting to alleviate specific threats to the Appalachian elktoe, the Service will seek additional research in this area.

Issue 16: One of the mining companies asked whether any specimens were found in 1993.

Service Response: During 1993, two specimens of the Appalachian elktoe were observed in a riffle area of the Nolichucky River (at a site where the species had been previously recorded) along the Yancey/Mitchell County line, North Carolina (personal observation); and several specimens (approximately 15 to 20) were observed by North Carolina Wildlife Resources Commission personnel (John Alderman and Christopher McGrath) and Service biologists in riffle and shoal areas of the Little Tennessee River in Swain County, North Carolina.

Issue 17: One of the mining companies asked whether current fluoride levels in the North Toe River are affecting the Appalachian elktoe.

Service Response: The Service is not aware of any information currently available that indicates that the allowable levels of fluoride, currently permitted under existing NPDES permits for the mining discharges into the North Toe River system, are having an adverse effect on the Appalachian elktoe in the Toe and Nolichucky Rivers.

During the surveys for the Appalachian elktoe in the Nolichucky River system that were conducted in 1991 and 1992 by the Service, the Service used maps that misidentified the Toe River as the North Toe River (these maps did not show a Toe River). Subsequently, in the September 3, 1993, proposed rule, the Service incorrectly identified the Appalachian elktoe as occurring in the North Toe River. This

species is present in the Toe River but is not present in the North Toe River (this has been corrected throughout this rule). The Toe River portion of Nolichucky River population of the Appalachian elktoe is currently located over 20 river miles from the nearest of the existing mining discharges.

Issue 18: Congressman Taylor, Congressman Ballenger, the Mitchell County Economic Development Commission, the Mayor of the town of Spruce Pine, three mining companies, and several other respondents questioned whether the Appalachian elktoe is truly endangered and requested that, prior to listing, the Service conduct further studies concerning the cause of the decline of the species and/or to determine whether the Nolichucky River population of the species is declining.

Service Response: Intensive surveys of both historic and potential habitat of the Appalachian elktoe have been conducted throughout the upper Tennessee River system—the historic range of the species (see "Background" section above). The results of these surveys reveal that the species has been eliminated from four of the eight rivers in which it is known to have historically occurred, including the Little River, the Swannanoa River, the Pigeon River, and the main stem of the French Broad River. It has also been eliminated from Talula Creek, and has essentially been eliminated from the Cane River (despite intensive surveys of this river in recent years, only one old adult specimen was found). This represents the loss of the species from at least two-thirds of its historic range. Only two relatively small, isolated populations of the Appalachian elktoe are known to survive.

The elimination of a species from the majority of its range and the isolating and confining of surviving populations to small areas, greatly increases the vulnerability of a species to extinction. It reduces the species' ability to respond to changes (natural or manmade) within its environment and to recover from impacts (large or repeated small scale impacts) to its numbers, that a species with widely dispersed, interconnected healthy populations would likely be able to overcome.

The Service does not have specific information to estimate numbers of individuals present in the Nolichucky River population of the Appalachian elktoe. Neither does the Service have specific data concerning whether this population is currently in decline, stable, or increasing.

The Service, the North Carolina Wildlife Resources Commission, the Tennessee Valley Authority, the Tennessee Technological University and other agencies and researchers have conducted extensive surveys of the Nolichucky River system, either specifically for the Appalachian elktoe or as part of monitoring or research on other species. The results of these surveys indicate that the Nolichucky River population of the Appalachian elktoe is currently restricted to a relatively short reach of the river system, that suitable habitat for the species is presently limited within the river system, and that where the species has been found it appears to exist in relatively low numbers. The Service believes it is endangered regardless of whether it is currently increasing, declining, or stable.

The Service believes there is sufficient information currently available that shows that the Appalachian elktoe has been eliminated from a significant portion of its historic range (see "Background" section above); and that the only two known surviving populations of the species are restricted in range, insufficiently protected by other existing regulatory mechanisms, are isolated from one another, and are vulnerable to many of the same factors that resulted in its extirpation elsewhere within its historic range. The Act requires the Service list such species.

Issue 19: The Mayor of the town of Spruce Pine and two other individuals stated that they felt there was not enough opportunity provided by the Service for public input regarding the potential listing of the Appalachian elktoe.

Service Response: The Service solicited comments concerning the potential listing of the Appalachian elktoe from all interested parties through notices of review (April 20, 1992, and August 21, 1992), the proposed rule (published September 3, 1993), the notice of the public hearing and reopening of the comment period (published January 21, 1994), the public hearing (held February 8, 1994), and associated notification letters and legal notices published in the local newspapers (see "Background" section and the first paragraph of "Summary of Comments and Recommendations" above).

Issue 20: One respondent inquired whether the government would pay Federal employees' salaries and attorney fees, and whether the government would pay citizens' salaries and attorney fees, if the citizens decide to take the "program" the Service plans to implement to court. The respondent did not specify what "program" he was referring to.

Service Response: Whether the government would provide representation to Service employees would be dependent upon the nature of the law suit. Whether the government would provide attorney fees to the plaintiff would also be dependent upon the nature and outcome of the law suit.

Issue 21: One respondent quoted the representative from the Tennessee Valley Authority who participated in the public hearing as saying that "the Appalachian elktoe would be used for cancer research" and he questioned how this could be if the species was endangered.

Service Response: The representative from the Tennessee Valley Authority was misquoted. He said that some species of freshwater mussels are being used in cancer research, because freshwater mussels do not develop tumors and appear to be immune to cancer. The rarity of the Appalachian elktoe will likely preclude the use of the species in such research efforts.

Issue 22: Nantahala Power and Light Company requested that the Service take immediate steps to develop and implement a recovery plan for the Appalachian elktoe.

Service Response: The Service will attempt to develop and distribute a draft recovery plan for the Appalachian elktoe within one year of date of this final rule, and a final recovery plan within two years of this final rule. The recovery plan will be developed through coordination with appropriate Federal and State agencies, county and local governments, individuals knowledgeable about freshwater mussels, and interested businesses, industries, and individuals.

Summary of Factors Affecting the Species

After a thorough review and consideration of all information available, the Service has determined that the Appalachian elktoe should be classified as an endangered species. Procedures found at Section 4(a)(1) of the Act (16 U.S.C. 1531 *et seq.*) and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act were followed. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in Section 4(a)(1). These factors and their application to the Appalachian elktoe (*Alasmidonta raveneliana*) are as follows:

A. The Present or Threatened Destruction, Modification, or Curtailment of its Habitat or Range

Historic and recent collection records for the Appalachian elktoe indicate that the species was once fairly widely distributed throughout the upper Tennessee River system in North Carolina, including the French Broad River system, the Little Tennessee River system, and the Nolichucky River system (Clarke 1981, Biggins 1990, and Gordon 1991). In Tennessee, the species is known only from its present distribution in the Nolichucky River. The species apparently no longer exists in the French Broad River system, where it was once fairly widely distributed; and, with the exception of one small population each in the Nolichucky River system and the main stem of the Little Tennessee River, the species has been eliminated from these river systems as well. The decline of this species throughout its range has been attributed to several factors, including siltation resulting from mining, logging, agricultural, and construction activities; runoff and discharge of organic and inorganic pollutants from industrial, municipal, agricultural, and other point and non-point sources; habitat alterations associated with impoundments, channelization, and dredging; and other natural and human-related factors that adversely modify the aquatic environment. Many of these same factors threaten the two remaining populations of the species.

The Little Tennessee River population, the healthiest of the two remaining populations, inhabits a relatively short stretch of the river located between Emory Lake at Franklin, Macon County, North Carolina, and Fontana Reservoir in Swain County, North Carolina. This population was likely reduced in size by the impoundment of these two reservoirs. The Nolichucky River population appears to be restricted to scattered pockets within a short reach of the main stem of the Nolichucky River in Unicoi County, Tennessee, and Mitchell and Yancey Counties, North Carolina, extending a short distance into the Toe River, Yancey and Mitchell Counties, North Carolina. A single, adult specimen was also collected a short distance up the Cane River (Nolichucky River system) in Yancey County, North Carolina.

The most immediate threats to both remaining populations appear to be associated with heavy silt loads and other pollutants (i.e., fertilizers, pesticides, heavy metals, oil, salts, organic wastes, etc.) from residential and industrial developments, road and highway construction/improvement projects, crop and livestock farming activities, and other land disturbance activities occurring throughout the rivers' watersheds. Much of the Nolichucky River in North Carolina contains heavy loads of sediments from past and ongoing land disturbance activities within its watershed, and suitable habitat for the Appalachian elktoe appears to be limited in this river system.

Also, because both extant populations of the Appalachian elktoe are restricted to short river reaches, each is extremely vulnerable to extirpation from a single catastrophic event, such as a toxic chemical spill or an activity resulting in a major river channel/habitat modification.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

This freshwater mussel species is not commercially valuable, but because it is extremely rare it could be sought by collectors. While collecting or other intentional take is not presently identified as a factor contributing to the species' decline, because the Appalachian elktoe is extremely restricted in range, such take could pose a significant threat to the species' continued existence if it should occur. Federal listing would help control any indiscriminate taking of individuals.

C. Disease or Predation

Since 1982, biologists and commercial mussel fishermen have reported mussel die-offs in rivers and lakes throughout the United States. The cause(s) of many of these die-offs is unknown, but disease has been suggested as a possible factor.

Shells of the Appalachian elktoe are often found in muskrat middens along the reach of the Little Tennessee River, where the species still exists, and occasionally in middens along the Nolichucky River. The species is also presumably consumed by other mammals, such as raccoons, otter, and mink. While predation is not thought to be a significant threat to a healthy mussel population, it could, as suggested by Neves and Odum (1989), limit the recovery of endangered mussel species or contribute to the local extirpation of mussel populations already depleted by other factors. Predation would be of primary concern to the Nolichucky River population of the Appalachian elktoe, which appears to be very small.

D. The Inadequacy of Existing Regulatory Mechanisms.

The States of North Carolina and Tennessee prohibit taking of fish and wildlife, including freshwater mussels, for scientific purposes without a State collecting permit. However, State regulations do not generally protect the species from other threats. Existing authorities available to protect aquatic systems, such as the Clean Water Act, administered by the Environmental Protection Agency (EPA) and the Army Corps of Engineers, have not been fully utilized and may have led to the degradation of aquatic environments in the Southeast Region, thus resulting in a decline of aquatic species. The Little Tennessee River population of the species is indirectly provided some Federal protection from Federal actions and activities through the Act, due to the fact that at least a portion of this population inhabits the same stretch of river as the federally threatened spotfin chub (*Cyprinella* [=*Hybopsis*] *monacha*) and the federally endangered little-wing pearly mussel (*Pegias fabula*). However, the Nolichucky River population of the species is not afforded this protection. Federal listing will provide additional protection for the Appalachian elktoe throughout its range by requiring Federal permits in order to take the species and by requiring Federal agencies to consult with the Service when activities they fund, authorize, or carry out may affect the species. Further, listing will require consultation with the EPA in relationship to water quality criteria, standards, and National Pollution Discharge Elimination System permits under the Clean Water Act; and implementation of actions to recover the species.

E. Other Natural or Manmade Factors Affecting Its Continued Existence.

Only two populations of this species are known to still exist. Both are relatively small, particularly the Nolichucky River population, and both are geographically isolated. This isolation prohibits the natural interchange of genetic material between populations, and the small population size reduces the reservoir of genetic variability within the populations. It is possible that both the remaining populations of the Appalachian elktoe may already be below the level required to maintain long-term genetic viability. Because the remaining populations are isolated, natural repopulation of an extirpated population would be impossible without human intervention.

The Service has carefully assessed the best scientific and commercial

information available regarding the past, present, and future threats faced by this species in determining to make this rule final. Based on this evaluation, the preferred action is to list the Appalachian elktoe as an endangered species. The species has been eliminated from the French Broad River system, and its range has been greatly reduced in the other two river systems (the Little Tennessee River and the Nolichucky River systems) in which the species historically occurred. Presently, only two small isolated populations are known to survive. These populations are threatened by a variety of factors, including road construction activities, residential and commercial development, mining activities, farming and logging activities, sewage and industrial effluent, and other manmade and natural factors adversely affecting the aquatic environment. Due to the species' history of population losses and the extreme vulnerability of the two surviving populations, endangered status appears to be appropriate for this species (see "Critical Habitat" section for a discussion of why critical habitat is not being proposed for the Appalachian elktoe).

Critical Habitat

Section 4(a)(3) of the Act requires that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be endangered or threatened. The Service's regulations (50 CFR 424.12(a)(1)) state that designation of critical habitat is not prudent when one or both of the following situations exist: (1) the species is threatened by taking or other activity and the identification of critical habitat can be expected to increase the degree of threat to the species or (2) such designation of critical habitat would not be beneficial to the species. The Service finds that designation of critical habitat is not prudent for this species. Such a determination would result in no known benefit to the Appalachian elktoe.

Section 7(a)(2) and regulations codified at 50 CFR Part 402 require Federal agencies to ensure, in consultation with and with the assistance of the Service, that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of listed species or destroy or adversely modify their critical habitat, if designated. Section 7(a)(4) requires Federal agencies to confer informally with the Service on any action that is likely to jeopardize the continued existence of a proposed species or result in the destruction or adverse modification of proposed critical habitat. (See "Available Conservation Measures" section for a further discussion of Section 7.) As part of the development of this rule, Federal and State agencies were notified of the Appalachian elktoe's general distribution, and they were requested to provide data on proposed Federal actions that might adversely affect the species. Three highway projects have been identified within, or in relatively close proximity to, occupied habitat of the Appalachian elktoe. The Service is currently involved in informal consultations regarding these projects. Should any future projects be proposed in areas inhabited by this mussel, the involved Federal agency will already have the general distributional data needed to determine if the species may be affected by their action; and if needed, more specific distributional information would be provided.

The Appalachian elktoe occupies very restricted stream reaches within only two river systems—the Little Tennessee River system and the Nolichucky River system. Any significant adverse modification or destruction of the species' habitat would likely jeopardize the species' continued existence. Therefore, no additional protection for the mussel would accrue from critical habitat designation that would not also accrue from listing of the species. When listed, habitat protection for the Appalachian elktoe will be accomplished through the Section 7 jeopardy standard and Section 9 prohibitions against take.

In addition, the Appalachian elktoe is very rare, and taking for scientific purposes and private collection could pose a threat if specific site information were released. The publication of critical habitat maps in the **Federal Register** and local newspapers and other publicity accompanying critical habitat designation could increase the collection threat and increase the potential for vandalism during the often controversial critical habitat designation process. The locations of populations of this species have consequently been described only in general terms in this proposed rule. Any existing precise locality data would be available to appropriate Federal, State, and local government agencies from the Service office described in the **ADDRESSES** section; from the Service's Raleigh Field Office, P.O. Box 33726, Raleigh, North Carolina 27636–3726; the Service's Cookeville Field Office, 446 Neal Street, Cookeville, Tennessee 38501, and from the North Carolina Wildlife Resources Commission, North Carolina Natural Heritage Program, Tennessee Wildlife Resources Agency, and Tennessee Department of Conservation.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required of Federal agencies and the prohibitions against taking and harm are discussed, in part, below.

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR Part 402. Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service. The Service has notified Federal agencies that may have programs that affect the species. Federal activities that occur and impact the species include, but are not limited to, the carrying out or the issuance of permits for reservoir construction, stream alterations, wastewater facility development, hydroelectric facility construction and operation, forestry operations, and road and bridge construction. It has been the experience of the Service, however, that nearly all Section 7 consultations can be resolved so that the species is protected and the project objectives met.

The Act and implementing regulations found at 50 CFR 17.21 set forth a series of general prohibitions and exceptions that apply to all endangered wildlife. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, or collect; or to attempt any of these), import or export, ship in interstate commerce in the course of a commercial activity, or sell or offer for sale in interstate or

foreign commerce any listed species. It also is illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to agents of the Service and State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving endangered wildlife species under certain circumstances. Regulations governing permits are at 50 CFR 17.22, and 17.23. Such permits are available for scientific purposes, to enhance the propagation or survival of the species, and/or for incidental take in connection with otherwise lawful activities.

It is the policy of the Service (59 FR 34272) to identify to the maximum extent practicable at the time a species is listed those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of the listing on proposed and ongoing activities within a species' range. During the public comment period the Service received inquiries about the effect listing would have on the mining industry and farming practices. As previously discussed in the Summary of Comments and Recommendations section, the Service believes that, based on the current available information, the existing discharges associated with the mining industry are not likely to be affected by this listing and will not result in a violation of section 9, provided these activities are carried out in accordance with existing regulations and permit requirements, such as, projects subject to section 404 of the Clean Water Act and discharges regulated under the National Pollutant Discharge Elimination System (NPDES). The Service is not aware of any current farming practices will result in a violation of section 9. Activities that the Service believes could potentially result in "take" of the Appalachian elktoe include, but are not limited to:

(1) Unauthorized collecting or handling of the species;

(2) Unauthorized destruction/alteration of the species habitat (i.e., in-stream dredging, rock removal, channelization, discharge of fill material, operation of heavy equipment within the stream channel, etc.);

(3) Violations of discharge permits;

(4) Pesticide applications in violation of label restrictions; and

(5) Illegal discharges or dumping of toxic chemicals, silt, fertilizers, pesticides, heavy metals, oil, organic wastes or other pollutants into waters supporting the species.

Questions regarding whether specific activities will constitute a violation of section 9 should be directed to the Field Supervisor of the Service's Asheville Office (see **ADDRESSES** section). Requests for copies of the regulations concerning listed animals and general inquiries regarding prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Southeast Regional Office, Ecological Services Division, Threatened and Endangered Species, 1875 Century Boulevard, Atlanta, Georgia 30345–3301 (Telephone 404/679–7099, Facsimile 404/679–7081).

National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to Section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of all references cited herein is available upon request from the Asheville field office (see **ADDRESSES** above)

Author

The primary author of this proposed rule is John A. Fridell, U.S. Fish and Wildlife Service, 330 Ridgefield Court, Asheville, North Carolina 28806 (704/665–1195, Ext. 225).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, and Transportation.

Regulation Promulgation

Accordingly, part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, is amended as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Amend § 17.11(h) for animals by adding the following, in alphabetical order under CLAMS, to the List of Endangered and Threatened Wildlife, to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*	*	*
CLAMS							
*	*	*	*	*	*	*	*
Elktoe, Appalachian	*Alasmidonta raveneliana.*	U.S.A. (NC, TN)	NA	E	563	NA	NA
*	*	*	*	*	*	*	*

Dated: August 31, 1994.

Mollie H. Beattie,

Director, Fish and Wildlife Service.

[FR Doc. 94–28935 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–55–P

Proposed Rules

Federal Register
Vol. 59, No. 225
Wednesday, November 23, 1994

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1079

[DA–95–07]

Milk in the Iowa Marketing Area; Notice of Proposed Revision of Pool Supply Plant Shipping Percentage

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed revision of rules.

SUMMARY: This notice invites written comments on a proposal to increase the percentage of a supply plant's receipts that must be delivered to fluid milk plants to qualify a supply plant for pooling under the Iowa Federal milk order. The applicable percentage would be increased by 10 percentage points, from 20 percent to 30 percent. The action is requested on behalf of Anderson-Erickson Dairy Company of Des Moines, Iowa, a proprietary distributing plant that is regulated under the order. Proponent contends that the action is needed to obtain an adequate supply of milk for fluid use.

DATES: Comments are due no later than November 30, 1994.

ADDRESSES: Comments (two copies) should be sent to USDA/AMS/Dairy Division, Order Formulation Branch, Room 2968, South Building, P.O. Box 96456, Washington, DC 20090–6456.

FOR FURTHER INFORMATION CONTACT: Constance M. Brenner, Marketing Specialist, USDA/AMS/Dairy Division, Order Formulation Branch, Room 2968, South Building, P.O. Box 96456, Washington, DC 20090–6456, (202) 720–7311.

SUPPLEMENTARY INFORMATION: The Regulatory Flexibility Act (5 U.S.C. 601–612) requires the Agency to examine the impact of a proposed rule on small entities. Pursuant to 5 U.S.C. 605(b), the Administrator of the Agricultural Marketing Service has certified that this action would not have a significant economic impact on a substantial number of small entities. Such action would tend to ensure that an adequate supply of fluid milk is available to consumers in the marketing area.

The Department is issuing this proposed rule in conformance with Executive Order 12866.

This proposed revision of rules has been reviewed under Executive Order 12778, Civil Justice Reform. This action is not intended to have retroactive effect. If adopted, this proposed action will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with the law and requesting a modification of an order or to be exempted from the order. A handler is afforded the opportunity for a hearing on the petition. After a hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has its principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after date of the entry of the ruling.

Notice is hereby given that, pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the provisions of § 1079.7(b)(1) of the order, the revision of certain provisions of the order regulating the handling of milk in the Iowa marketing area is being considered for the months of December 1, 1994 through March 31, 1994.

All persons who desire to submit written data, views or arguments about the proposed revision should send two copies of their views to USDA/AMS/Dairy Division, Order Formulation Branch, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456 by the 7th day after publication of this notice in the **Federal Register**. The filing period is limited to seven days because proponent asked that this revision be effective for the period of December 1, 1994 through March 31, 1995.

All written submissions made pursuant to this notice will be made available for public inspection in the Dairy Division during regular business hours (7 CFR 1.27(b)).

Statement of Consideration

The provision proposed for revision is the percentage of a supply plant's receipts required to be shipped to pool distributing plants pursuant to § 1079.7(b) of the Iowa Federal milk order (Order 79). As proposed, the percentage of a supply plant's receipts that must be shipped to pool distributing plants (fluid milk plants) if the supply plant is to be considered a pool plant would be increased by the maximum allowable 10 percentage points, from 20 percent to 30 percent, for the period December 1, 1994 through March 31, 1995.

Section 1079.7(b)(1) allows the Director of the Dairy Division to reduce or increase a pool supply plant's minimum shipping requirement by up to 10 percentage points to prevent uneconomic milk shipments or to assure an adequate supply of milk for fluid use.

Anderson-Erickson Dairy Company (A–E), a fluid milk processing plant that is a pool distributing plant under Order 79, requested that the shipping percentage be increased. The handler's request states that although milk supplies on the market are plentiful, suppliers are unable or unwilling to supply milk to A–E at the present market price, leaving A–E short of its needs for fluid milk by 3 loads of milk per day. A–E cites the $1.93 difference between Class III and Class III–A prices as a factor in causing milk supplies to be retained in nonfat dry milk operations instead of being made available to the fluid market.

In view of the foregoing, it may be appropriate to increase the shipping percentage requirements for pool supply plants under Order 79 for the period December 1, 1994 through March 31, 1995.

List of Subjects in 7 CFR Part 1079

Milk marketing orders.

The authority citation for 7 CFR Part 1079 continues to read as follows:

Authority: (Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674).

Dated: November 21, 1994.
Richard M. McKee,
Director, Dairy Divison.
[FR Doc. 94–29082 Filed 11–22–94; 8:45 am]
BILLING CODE 3410–02–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430

[Docket No. EE–RM–93–801]

Energy Conservation Program for Consumer Products (Energy Conservation Standards for Three Types of Consumers Products)

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Supplemental Advance Notice of Proposed Rulemaking; extending comment period and rescheduling public hearing.

SUMMARY: Because of requests from the Air Conditioning and Refrigeration Institute, the Gas Appliance Manufacturers Association, the National Electrical Manufacturers Association, the Association of Home Appliance Manufacturers, the National Coal Association, the Edison Electric Institute, the Center for Energy and Economic Development, the National Rural Electric Cooperative Association, and the Southern Company, and the complexity of the information contained in the Supplemental Advance Notice of Proposed Rulemaking, the Department of Energy has decided to extend the comment period by 60 days and reschedule the public hearing. This notice announces that the comment period that was to be closed on December 6, 1994, will be extended to February 6, 1995, and the public hearing that was scheduled for November 17, 1994, will be held on January 19, 1995.

DATES: Written comments in response to this document must be received by February 6, 1995. Oral views, data, and arguments may be presented at a public hearing to be held in Washington, D.C., on January 19, 1995. Requests to speak at the public hearing must be received by the Department no later than 4 p.m. Monday, January 9, 1995. Ten copies of statements to be given at the public hearing must be received by the Department no later than 4 p.m., Friday, January 13, 1995.

The length of each presentation is limited to 20 minutes.

ADDRESSES: Written comments, oral statements, requests to speak at the hearing, and requests for speaker lists are to be submitted to: U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, EE–431, Energy Conservation Program for Consumer Products, Docket No. EE–RM–93–801, Room 5E–066, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586–9127.

The hearing will begin at 9:30 a.m., on January 19, 1995, and will be held at the U.S. Department of Energy, Forrestal Building, Room 1E–245, 1000 Independence Avenue, SW, Washington, DC.

Requests may be hand delivered to such address between the hours of 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Requests should be labeled "Energy Conservation Program for Consumer Products (Energy Conservation Standards for Three Types of Consumers Products)," (Docket No. EE–RM–93–801) both on the document and on the envelope.

Copies of the transcript of the public hearing and public comments received may be read and/or photocopied at the DOE Freedom of Information Reading Room, U.S. Department of Energy, Forrestal Building, Room 1E–190, 1000 Independence Avenue, SW, Washington, DC, 20585, (202) 586–6020 between the hours of 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Dr. Barry P. Berlin, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Mail Station EE–43, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9127

Eugene Margolis, Esq., U.S. Department of Energy, Office of the General Counsel, Mail Station GC–72, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9507

SUPPLEMENTARY INFORMATION: The Department published a Supplementary Advance Notice of Proposed Rulemaking (SANOPR) on October 7, 1994, entitled "Energy Conservation Program for Consumer Products: Supplemental Advance Notice of Proposed Rulemaking Regarding Energy Conservation Standards for Three Types of Consumer Products." (59 FR 51140).

In earlier Advance Notices of Proposed Rulemaking (Docket Nos. CE–RM–93–801 and EE–RM–94–403), the Department expressed its intention to consider more explicitly environmental and energy security externalities in the development of future appliance efficiency standards. In this regard, the Department indicated that it would attempt to establish monetary values for these externalities if a sound analytical basis could be found. The Supplemental Advance Notice identified and requested comment on issues surrounding possible analytical bases for such externality values.

While the Supplemental Advance Notice is referenced in advance notices affecting two rulemakings, the Department welcomes comments from all parties interested in the energy conservation program for consumer products. DOE requests that interested parties focus their comments on the use of externalities in the development of appliance standards, rather than on the merits of considering externalities in formulating other regulations or energy-related policies more generally.

The Department emphasizes that it has not reached conclusions on the analytical issues raised in the Supplemental Advance Notice and that public comments on these issues will assist the Department in determining whether a sound analytical basis exists for establishing monetary values for externalities that might be used in developing appliance efficiency standards.

In their letter of October 25, 1994, to the Department, the Air Conditioning and Refrigeration Institute, Gas Appliance Manufacturers Association, National Electrical Manufacturers Association, and Association of Home Appliance Manufacturers had requested that the Department withdraw the SANOPR because of alleged legal, theoretical, and practical difficulties with proceeding with it. Failing that, their letter requested that the Department postpone the hearing date and extend the close of the comment period.

In its letter of October 26, 1994, to the Department, the National Coal Association cited the complexity of the issues raised in the SANOPR, involving "economic theory," the correct role of regulatory process in the U.S., and the scientific basis for the proposed acting, among other things, and requested extending the comment period to February 6, 1995, and rescheduling the hearing for January 16, 1995.

In its letter of October 27, 1994, to the Department, the Edison Electric Institute cited the need for additional time to evaluate the questions raised by the SANOPR, and also suggested extending the comment period to February 6, 1995.

In its letter of October 28, 1994, to the Department, the Center for Energy and

Economic Development cited the complexity of the issues raised by the SANOPR, and requested extending the comment period to February 6, 1995.

In its letter of October 28, 1994, the National Rural Electric Cooperative Association noted that the issue raised by the SANOPR is highly controversial and complex, and requested an extension of the comment period to have time to "gather sufficient and pertinent information to be of service to DOE."

In its letter of November 1, 1994, to the Department, the Southern Company noted that the SANOPR raises "numerous and far reaching issues that will impact our electric customers and shareholders," and requested that the Department extend the comment period to February 6, 1995, and postpone the public hearing for at least thirty days (from November 17, 1994).

Based on these representations, the Department is extending the comment period to February 6, 1995, and rescheduling the hearing for January 19, 1995. This Notice is being published in the **Federal Register** after November 17, 1994, the originial date of the hearing. Prior thereto, the Department contacted by telephone all parties that requested to speak at the hearing and informed them of the rescheduled date.

Issued in Washington, D.C., November 18, 1994.

Peter S. Fox-Penner,

Principal Deputy Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 94-28944 Filed 11-22-94; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 93-CE-51-AD]

Airworthiness Directives; de Havilland DHC-6 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to supersede Airworthiness Directive (AD) 83-26-05 and AD 86-15-08, which currently require repetitively inspecting the horizontal stabilizer attachment fittings for cracks or looseness on certain de Havilland DHC-6 series airplanes, and, if a cracked or loose part is found, modifying the horizontal stabilizer. The proposed action would incorporate an improved modification that, when incorporated, provides terminating action for the existing AD's. Reports of loose horizontal stabilizer attachment fittings on airplanes with the existing inspection-terminating modification incorporated prompted the proposed action. The actions specified by the proposed AD are intended to prevent separation of the horizontal stabilizer from the airplane caused by a cracked attachment fitting, and subsequent loss of control of the airplane.

DATES: Comments must be received on or before January 27, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 93-CE-51-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from de Havilland, Inc., 123 Garratt Boulevard, Downsview, Ontario, Canada, M3K 1Y5. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Jon Hjelm, Aerospace Engineer, FAA, New York Aircraft Certification Office, 181 South Franklin Avenue, Room 202, Valley Stream, New York 11581; telephone (516) 791-6220; facsimile (516) 791-9024.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA- public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 93-CE-51-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 93-CE-51-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

Transport Canada, which is the airworthiness authority for Canada, recently notified the FAA that an unsafe condition may exist on de Havilland DHC-6 series airplanes. Transport Canada reports that the horizontal stabilizer attachment fittings have cracked on several of the above referenced airplanes that were in compliance with AD 83-26-05, Amendment 39-4793, and AD 86-15-08, Amendment 39-5362.

AD 83-26-05 currently requires repetitively inspecting the horizontal stabilizer attachment fittings on de Havilland DHC-6 series airplanes, and replacing any cracked fitting with a new fitting of the same part number or incorporating Modification 6/1808 and 6/1809.

AD 86-15-08 currently requires incorporating improved modifications (Modifications 6/1855 and 6/1856) for de Havilland DHC-6 series airplanes that have Modifications 6/1808 and 6/1809 incorporated.

De Havilland has issued Service Bulletin (SB) No. 6/512, dated October 25, 1991, which specifies procedures for (1) inspecting the horizontal stabilizer attachment fittings for cracks; and (2) replacing these fittings. This service bulletin replaces de Havilland SB No. 6/475, which included procedures for incorporating Modifications 6/1855 and 6/1856. Transport Canada classified de Havilland SB No. 6/512 as mandatory and issued Transport Canada AD CF-92-04, dated January 30, 1992, in order to assure the continued airworthiness of these airplanes in Canada.

This airplane model is manufactured in Canada and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral

airworthiness agreement. Pursuant to this bilateral airworthiness agreement, Transport Canada has kept the FAA informed of the situation described above. The FAA has examined the findings of Transport Canada, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop in other de Havilland DHC–6 series airplanes of the same type design, the proposed AD would supersede both AD 83–26–05 and AD 86–15–08 with a new AD that would require repetitively inspecting the horizontal stabilizer attachment fittings for cracks; and, if a cracked fitting is found, replacing with a serviceable fitting, part number (P/N) C6TPM1049–27 (forward fitting) or C6TPM1050–27 (rear fitting), and incorporating Modifications 6/1890, 6/1891, and 6/1892. The proposed action would also require the eventual incorporation of the above-referenced modifications for airplanes that have Modifications 6/1808 and 6/1809 incorporated. The proposed action would be accomplished in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of de Havilland SB 6/512, dated October 25, 1991.

The FAA estimates that 169 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 1 workhour per airplane to accomplish the proposed inspection and it would take approximately 10 workhours to accomplish the modification for those airplanes having Modifications 6/1808 and 6/1809 incorporated, and that the average labor rate is $60 per hour. The FAA has no way of knowing how many airplanes have incorporated these modifications. In estimating the total cost impact of the proposed AD on U.S. operators, the FAA is only using the inspection criteria (1 workhour). With this in mind and based on those figures above, the total cost impact of the proposed AD upon U.S. operators of the affected airplanes is estimated to be $10,140. This figure only includes the cost for the initial inspection and does not include replacement costs if an attachment fitting was found cracked nor does it include repetitive inspection costs. The FAA has no way of determining how many horizontal stabilizer attachment fittings may be cracked or how many repetitive inspections each owner/operator may incur.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing AD 83–26–05, Amendment 39–4793, and AD 86–15–08, Amendment 39–5362, and by adding a new AD to read as follows:

De Havilland: Docket No. 93–CE–51–AD; Supersedes AD 83–26–05, Amendment 39–4793, and AD 86–15–08, Amendment 39–5362.

Applicability: Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes, serial number 3 through 820, certificated in any category.

Compliance: Required as indicated, unless already accomplished.

To prevent separation of the horizontal stabilizer from the airplane caused by a cracked attachment fitting, and subsequent loss of control of the airplane, accomplish the following:

(a) For airplanes without Modification Nos. 6/1808 and 6/1809 incorporated, accomplish the following:

(1) Within the next 50 hours time-in-service (TIS) after the effective date of this AD or 800 hours TIS after the last inspection required by superseded AD 83–26–05, whichever occurs later, and thereafter at intervals not to exceed 800 hours TIS, inspect the horizontal stabilizer forward and rear attachment fittings for cracks in accordance with de Havilland Service Bulletin (SB) No. 6/438, Revision D, dated March 28, 1986.

(2) If any cracks are found, prior to further flight, replace the cracked fitting with a serviceable fitting, part number (P/N) C6TPM1049–27 (forward fitting) or P/N C6TPM1050–27 (rear fitting), and incorporate Modifications 6/1890, 6/1891, and 6/1892 at each replacement fitting location in accordance with and as specified in de Havilland SB No. 6/513, dated October 25, 1991

(b) For airplanes that have Modifications 6/1808 and 6/1809 incorporated, accomplish the following:

(1) Within the next 400 hours time-in-service after the effective date of this AD, and thereafter at intervals not to exceed 800 hours TIS, inspect the rivets attaching the fittings to the horizontal stabilizer forward and rear spars for looseness in accordance with the III ACCOMPLISHMENT INSTRUCTIONS A. INSPECTION section of de Havilland SB No. 6/513, dated October 25, 1993.

(2) If rivets are found loose, prior to further flight, incorporate Modifications 6/1890, 6/1891, and 6/1892 in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of de Havilland SB No. 6/513, dated October 25, 1993.

(3) Within the next 2,400 hours TIS after the effective date of this AD, unless already accomplished as required by paragraph (b)(2) of this AD, incorporate Modifications 6/1890, 6/1891, and 6/1892 on all four horizontal stabilizer fittings in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of de Havilland SB No. 6/513, dated October 25, 1993.

(c) Incorporating Modifications 6/1890, 6/1891, and 6/1892 on all four horizontal stabilizer fittings in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of de Havilland SB No. 6/513, dated October 25, 1993, is considered terminating action for the repetitive inspection requirements of this AD.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, New York Aircraft Certification Office (ACO), FAA, 181 South Franklin Avenue, Room 202, Valley Stream, New York 11581. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note: Information concerning the existence of approved alternative methods of

compliance with this AD, if any, may be obtained from the New York ACO.

(f) All persons affected by this directive may obtain copies of the document referred to herein upon request to de Havilland, Inc., 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5 Canada; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(g) This amendment supersedes AD 83–26–05, Amendment 39–4793, and AD 86–15–08, Amendment 39–5362. Issued in Kansas City, Missouri, on November 16, 1994.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–28884 Filed 11–22–94; 8:45 am]

BILLING CODE 4910–13–P

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14 CFR Part 73

[Airspace Docket No. 94–ASO–9]

Proposed Expansion of Restricted Area R–6002, Poinsett-Sumter, SC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to raise the upper limit of Restricted Area R–6002 from the current 13,000 feet mean sea level (MSL), to and including Flight Level (FL) 230, in order to provide airspace for high angle bomb delivery training at the Poinsett Range. As amended, the existing Restricted Area R–6002 would be redesignated R–6002A, and two new areas overlying R–6002A would be designated as R–6002B and R–6002C. This amendment would also change the name of the using agency for the restricted areas.

DATES: Comments must be received on or before January 9, 1995.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Air Traffic Division, ASO–500, Docket No. 94–ASO–9, Federal Aviation Administration, P.O. Box 20636, Atlanta, GA 30320.

The official docket may be examined in the Rules Docket, Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, DC, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Military Operations Program Office (ATM–420), Office of Air Traffic System Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–9361.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 94–ASO–9." The postcard will be date/time stamped and returned to the commenter. Send comments on environmental and land-use aspects to: HQACC/CEVA, 129 Andrews, Suite 102, Langley Air Force Base (AFB), VA 23665–2769. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–220, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–3485. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 73 of the Federal Aviation Regulations (14 CFR part 73) to raise the upper limit of Restricted Area R–6002, Poinsett-Sumter, SC, from the current 13,000 feet MSL up to and including FL 230. The horizontal boundaries of the restricted area would not be changed by this proposal. The existing Restricted Area R–6002 would be redesignated as R–6002A from the surface to but not including 13,000 feet MSL. Two new subareas would be established directly above R–6002A: R–6002B from 13,000 feet MSL to but not including FL 180; and R–6002C from FL 180 to and including FL 230. This configuration would facilitate the real-time utilization of airspace with the B and C subareas being activated when needed for high angle delivery training. This amendment would also change the name of the using agency for the restricted areas to reflect the redesignation of the 363rd Fighter Wing at Shaw AFB as the 20th Fighter Wing. The U.S. Air Force requested an increase in the vertical limits of R–6002 in order to conduct high altitude/high angle bomb delivery training. R–6002 does not currently have sufficient vertical airspace to accomplish this training. The coordinates for this airspace docket are based on North American Datum 83. Section 73.60 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8B dated March 9, 1994.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

An environmental review of this proposal will be conducted by the U.S. Air Force and the FAA prior to an FAA final decision on the proposal. The results of the review will be addressed in any subsequent rulemaking action.

List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 73 as follows:

PART 73—[AMENDED]

1. The authority citation for 14 CFR part 73 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510, 1522; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 73.60 [Amended]

2. Section 73.60 is amended as follows:

R–6002 Poinsett-Sumter, SC [Removed]

R–6002A Poinsett-Sumter, SC [New]

Boundaries. Beginning at lat. 33°54'25" N., long. 80°24'11" W.; to lat. 33°46'26" N., long. 80°23'11" W.; to lat. 33°44'28" N., long. 80°31'41" W.; to lat. 33°50'14" N., long. 80°31'02" W.; to lat. 33°53'38" N., long. 80°31'02" W.; to the point of beginning.

Designated altitudes. Surface to but not including 13,000 feet MSL.

Time of designation. 0600–2400 local time Monday–Friday; 0800–1600 local time Saturday; other times by NOTAM at least 8 hours in advance.

Controlling agency. FAA, Jacksonville ARTCC.

Using agency. U.S. Air Force, 20 FW, Shaw AFB, SC.

R–6002B Poinsett-Sumter, SC [New]

Boundaries. Beginning at lat. 33°54'25" N., long. 80°24'11" W.; to lat. 33°46'26" N., long. 80°23'11" W.; to lat. 33°44'28" N., long. 80°31'41" W.; to lat. 33°50'14" N., long. 80°31'02" W.; to lat. 33°53'38" N., long. 80°31'02" W.; to the point of beginning.

Designated altitudes. 13,000 feet MSL to but not including FL 180.

Time of designation. 0600–2400 local time Monday–Friday; 0800–1600 local time Saturday; other times by NOTAM at least 8 hours in advance.

Controlling agency. FAA, Jacksonville ARTCC.

Using agency. U.S. Air Force, 20 FW, Shaw AFB, SC.

R–6002C Poinsett-Sumter, SC [New]

Boundaries. Beginning at lat. 33°54'25" N., long. 80°24'11" W.; to lat. 33°46'26" N., long. 80°23'11" W.; to lat. 33°44'28" N., long. 80°31'41" W.; to lat. 33°50'14" N., long. 80°31'02" W.; to lat. 33°53'38" N., long. 80°31'02" W.; to the point of beginning.

Designated altitudes. FL 180 to FL 230.

Time of designation. 0600–2400 local time Monday–Friday; 0800–1600 local time Saturday; other times by NOTAM at least 8 hours in advance.

Controlling agency. FAA, Jacksonville ARTCC.

Using agency. U.S. Air Force, 20 FW, Shaw AFB, SC.

Issued in Washington, DC, on November 15, 1994.

Harold W. Becker,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 94–28918 Filed 11–22–94; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 284

[Docket No. RM93–4–006]

Standards for Electronic Bulletin Boards Required Under Part 284 of the Commission's Regulations

November 17, 1994.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of filing and opportunity to file comments.

SUMMARY: The Federal Energy Regulatory Commission (Commission) has received a filing from the Electronic Bulletin Board (EBB) Working Group requesting modifications to the Capacity Release Data Sets and EDI Implementation Guide. The Working Group proposed to add fields in the Award Data Set for reporting the maximum tariff rate relating to capacity posted for release at the time the offer to release is made. The proposed fields would report the maximum reservation rate and maximum volumetric rate for released capacity and are optional fields. The Commission is affording interested persons an opportunity to file comments on this filing.

DATES: Comments due by November 29, 1994.

ADDRESSES: Comments should be filed at: Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT:

Michael Goldenberg, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, (202) 208–2294

Marvin Rosenberg, Office of Economic Policy, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, (202) 208–1283

Brooks Carter, Office of Pipeline and Producer Regulation, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, (202) 208–0292

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in Room 3104, 941 North Capitol Street NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208–1397. To access CIPS, set your communications software to use 300, 1200, or 2400 bps, full duplex, no parity, 8 data bits, and 1 stop bit. CIPS can also be accessed at 9600 bps by dialing (202) 208–1781. The full text of this notice will be available on CIPS for 30 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in Room 3104, 941 North Capitol Street, NE., Washington, DC 20426.

Notice of Filing and Opportunity to File Comments

November 17, 1994.

Take notice that on November 4, 1994, the Electronic Bulletin Board (EBB) Working Group submitted requested modifications to the Capacity Release Data Sets and EDI Implementation Guide. The Working Group proposed to add fields in the Award Data Set for reporting the maximum tariff rate relating to capacity posted for release at the time the offer to release is made. The proposed fields would report the maximum reservation rate and maximum volumetric rate for released capacity and are optional fields. The filing also contains proposed revisions to the EDI implementation guide relating to this change.

Any person desiring to submit comments on this filing should file such comments with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 on or before November 29, 1994.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 94–28924 Filed 11–22–94; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 915

Iowa Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening and extension of public comment period on proposed amendment.

SUMMARY: OSM is announcing the receipt of revisions to a previously proposed amendment to the Iowa permanent regulatory program (hereinafter, the "Iowa Program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA), and is reopening the public comment period on the proposed amendment. The revised amendment proposes further changes of the Iowa regulations pertaining to permit revisions, bond release applications, and individual civil penalties. The amendment is intended to revise the State program to be consistent with the corresponding Federal standards, clarify ambiguities, and improve operational efficiency.

This document sets forth the times and locations that the Iowa program and proposed amendment to that program are available for public inspection and the reopened comment period during which interested persons may submit written comments on the proposed amendment.

DATES: Written comments must be received by 4 p.m., c.s.t. December 8, 1994.

ADDRESSES: Written comments should be mailed or hand delivered to Michael C. Wolfrom at the address listed below.

Copies of the Iowa program, the proposed amendment, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Kansas City Field Office.

Michael C. Wolfrom, Acting Director, Kansas City Field Office, Office of Surface Mining Reclamation and Enforcement, 934 Wyandotte, Room 500, Kansas City, MO 64105 Telephone: (816) 374–6405.

Iowa Department of Agriculture and Land Stewardship, Division of Soil Conservation, Wallace State Office Building, East 9th and Grand Streets, Des Moines, Iowa 50319; Telephone: (515) 281–6147.

FOR FURTHER INFORMATION CONTACT: Michael C. Wolfrom, Telephone: (816) 374–6405.

SUPPLEMENTARY INFORMATION:

I. Background on the Iowa Program

On January 21, 1981, the Secretary of the Interior conditionally approved the Iowa program. General background information on the Iowa program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Iowa program can be found in the January 21, 1981, **Federal Register** (46 FR 5885). Subsequent actions concerning Iowa's program and program amendments can be found at 30 CFR 915.15 and 915.16.

II. Discussion of Proposed Amendment

By letter dated April 13, 1994 (Administrative Record No. IA–397), Iowa submitted a proposed amendment to its program pursuant to SMCRA. Iowa submitted the proposed amendment with the intent of satisfying the required program amendments at 30 CFR 915.16 (a) and (b) and at the State's own initiative to improve its program.

OSM announced receipt of the proposed amendment in the May 5, 1994, **Federal Register** (59 FR 23177) and, in the same document, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period ended on June 6, 1994. The public hearing scheduled for May 31, 1994, was not held because no one requested an opportunity to testify.

During its review of the amendment, OSM identified several concerns relating to the provisions of the proposed amendment. OSM notified Iowa of the concerns by letter dated October 3, 1994 (Administrative Record No. IA–407), which identified eight deficiencies and one suggestion concerning the April 13, 1994, amendment submission. By letter dated November 8, 1994 (Administrative Record No. IA–408), Iowa submitted a revised amendment. This new amendment submission contains further revisions that are discussed briefly below:

(1) IAC 27–40.32 Permit Revisions

Iowa revises these regulations to require that all items incorporated into an approved permit must be addressed by application for either an amendment or a revision; removes the redundant incorporation by reference of 30 CFR 774.11 (b) and (c); deletes a phrase referring to conditions of the approved permit; establishes that amendments as well as revisions are subject to Part 9 of the Iowa rules; establishes the Division's intent that replacement documentation for amendments as well as revisions must describe changes to be made in the same detail as was required in the original permit; adds a reference to cultural resources as a consideration when determining significant departures from the original permit; and adds a third criterion for approval of a revision, requiring that applicable provisions of the written permit findings also be met.

(2) IAC 27–40.51(7) Applications for Bond Release

Iowa establishes a 30-day period in which the Division will make a determination of completeness of the bond release application.

(3) IAC 27–40.75(2) Definition of "Violation, Failure, or Refusal."

Iowa revises the definition to include applicable references to appropriate Iowa regulations.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Iowa program.

Written comments should be specific, pertain only to the issue proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Kansas City Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

IV. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Compliance With the National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National

Environmental Policy Act [42 U.S.C. 4332(2)(C)].

Compliance With the Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Compliance With Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsection (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the requirements of 30 CFR Parts 739, 731, and 732 have been met.

Compliance With the Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq*).

List of Subjects in 30 CFR Part 915

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 17, 1994.

Charles E. Sandberg,

Acting Assistant Director, Western Support Center.

[FR Doc. 94–28895 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–05–M

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30 CFR Part 918

Louisiana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Louisiana regulatory program (hereinafter, the "Louisiana program") under the Surface Mining Control and Reclamation Act of 1977. The proposed amendment consists of revisions to Louisiana's revegetation success regulations and a policy statement pertaining to tree stocking for forest land. The amendment is intended to revise the Louisiana program to be consistent with the corresponding Federal regulations.

DATES: Written comments must be received by 4:00 p.m., c.s.t. December 23, 1994. If requested, a public hearing on the proposed amendment will be held on December 19, 1994. Requests to present oral testimony at the hearing must be received by 4:00 p.m., c.s.t. on December 8, 1994. Any disabled individual who has need for a special accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: Written comments should be mailed or hand delivered to James H. Moncrief at the address listed below.

Copies of the Louisiana program, the proposed amendment, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Tulsa Field Office.

James H. Moncrief, Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 5100 East Skelly Drive, Suite 550, Tulsa, OK 74135–6548

Louisiana Department of Natural Resources, Office of Conservation, P.O. Box 94275, Baton Rouge, Louisiana 70804–9275, Telephone: (504) 342–5540

FOR FURTHER INFORMATION CONTACT: James H. Moncrief, Telephone: (918) 581–6430.

SUPPLEMENTARY INFORMATION:

I. Background on the Louisiana Program

On October 10, 1980, the Secretary of the Interior conditionally approved the Louisiana program. General background information on the Louisiana program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Louisiana program can be found in the October 10, 1980, **Federal Register** (45 FR 67340). Subsequent actions concerning Louisiana's program and program amendments can be found at 30 CFR 918.15 and 918.16.

II. Proposed Amendment

By letter dated November 2, 1994, Louisiana submitted a proposed amendment to its program pursuant to SMCRA (administrative record No. LA–351). Louisiana submitted the proposed amendment in response to the required program amendments at 30 CFR 918.16 (a) and (b) with the intent of making its program consistent with the corresponding Federal regulations.

Louisiana proposes to recodify Louisiana Surface Mining Regulations (LSMR) § 53123 as § 5423.

Louisiana also proposes to revise LSMR 5423.B.4, standards for success of revegetation at final bond release on reclaimed lands developed for forestry. Existing LSMR 5423.B.4 requires that "[a]t the time of final bond release there shall be 450 well-distributed free-to-grow live pine trees of the same age per acre or 250 well-distributed live hardwood trees of the same age per acre" and that "[c]countable stems shall be a minimum of three years old." Louisiana proposes to revise LSMR 5423.B.4 to include the requirement that countable tree stems used in determining the success of stocking and the adequacy of the plant arrangement shall "have utility for the approved forestry postmining land use and be healthy." Louisiana also proposes Policy Statement No. PS–5 to clarify that 100 percent of the threes counted to determine revegetation success must be in place for a minimum of 60 percent of the minimum responsibility period (i.e., a minimum 3 years of the minimum 5-year responsibility period).

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR

732.15. If the amendment is deemed adequate, it will become part of the Louisiana program.

1. Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under "DATES" or at locations other than the Tulsa Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

2. Public Hearing

Persons wishing to testify at the public hearing should contact the person listed under FOR FURTHER INFORMATION CONTACT by 4:00 p.m., c.s.t. on December 8, 1994. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to testify at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to testify have been heard. Persons in the audience who have not been scheduled to testify, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to testify and persons present in the audience who wish to testify have been heard.

3. Public Meeting

If only one person requests an opportunity to testify at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under FOR FURTHER INFORMATION CONTACT. All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under ADDRESSES. A written summary of each meeting will be made a part of the administrative record.

IV. Procedural Determinations

1. Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

2. Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

3. National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA ((30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act ((42 U.S.C. 4332(2)(C)).

4. Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

5. Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal that is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 918

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 17, 1994.

Charles E. Sandberg,

Acting Assistant Director, Western Support Center.

[FR Doc. 94–28894 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–05–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 68

[CC Docket No. 87–124; FCC 94–280]

Establishment of an Advisory Committee to Negotiate Regulations

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this Public Notice, the Commission seeks comment on establishing an Advisory Committee to negotiate regulations to specify the requirements for hearing aid compatible (HAC) telephones in workplaces, hospitals, certain other health care facilities, prisons, hotels, and motels.

DATES: Interested parties may file comments and nominations for Committee membership on or before December 23, 1994.

ADDRESSES: Comments and/or nominations should be sent to the Office of the Secretary, CC Docket No. 87–124, Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT:

John Walker, Common Carrier Bureau, 2025 M Street, NW., Washington, DC 20554 (202) 634–1820 or (202) 632–0484 (TTY).

SUPPLEMENTARY INFORMATION:

FCC Asks for Comments and Nominations for Membership Regarding the Establishment of an Advisory Committee to Negotiate Regulations

Released: November 7, 1994.

1. The Commission hereby seeks comment on establishing an Advisory Committee to negotiate regulations to specify the requirements for hearing aid compatible (HAC) telephones in workplaces, hospitals, certain other health care facilities, prisons, hotels and motels. The negotiations are to assist the

Commission in developing regulations that, among other things, will determine whether to lift the suspension of enforcement of § 68.112(b) (1), (3), and (5) of the Commission's rules. 47 CFR 68.112(b) (1), (3), (5). Those sections require that all telephones in all workplaces, hospitals, certain other health care facilities, prisons, hotels and motels be hearing aid compatible by May 1, 1993 for establishments with 20 or more employees and by May 1, 1994 for establishments with fewer than 20 employees. *See Access to Telecommunications Equipment and Services by the Hearing Impaired and Other Persons with Disabilities*, Report and Order, in FCC 92–217, 57 FR 27184 (June 4, 1992). The negotiating committee would be created under the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, and the Negotiated Rulemaking Act of 1990 (NRA), Pub. L. 101–648, November 28, 1990, and would consist of representatives of the interests that will be significantly affected by these rules.

2. On April 13, 1993, the Commission suspended until further notice enforcement of the requirement adopted in 1992 that all telephones in all workplaces employing 20 or more persons be hearing aid compatible by May 1, 1993. In addition, the Commission also suspended enforcement of the requirement that all telephones in workplaces employing fewer than 20 employees be hearing aid compatible by May 1, 1994. The Commission suspended enforcement of other requirements that telephones in all hospitals, certain other health care facilities, prisons, hotels and motels be hearing aid compatible by May 1, 1993 for establishments with 20 or more employees, and by May 1, 1994 for establishments with fewer than 20 employees. The Commission suspended enforcement of the rules for these telephones only if an alternative means of signalling life-threatening situations is available in such confined settings. The Commission previously had required telephones in workplace common areas, at the work stations of employees with hearing disabilities, and in areas where emergencies might require HAC telephones to be HAC.

Shortly before the effective date of the more stringent regulations, the Commission received numerous complaints from organizations alleging an inability to meet the deadline. The complaints raised legal and practical problems with the new HAC requirements, asserting that the number of phones to be retrofitted and the cost of doing so were much greater than originally envisioned and that retrofitters were unable to meet the demand. Some stated that they would be forced to remove telephones from use altogether to avoid violating HAC requirements, raising safety concerns. Finally, many claimed that the new retrofitting requirements violated the Hearing Aid Compatibility Act of 1988, which prohibits the Commission from requiring the retrofitting of any telephones other than coin-operated telephones or those provided for emergency use.

On May 12, 1993, the Alexander Graham Bell Association (the Association) filed an Emergency Request to Reinstate Enforcement of the rules. The Association argues that the suspension of enforcement violated section 553(b)(3) of the Administrative Procedure Act. Seventeen parties filed in opposition to the petition, and six parties filed in support of the petition, which is pending before the Commission.

I. Regulatory Negotiation

3. Regulatory Negotiation is a technique through which the Commission seeks to develop better regulations in a less adversarial setting. Negotiations are conducted through an Advisory Committee chartered under FACA. The goal for the Committee is to reach consensus on the language or substance of appropriate rules. If a consensus is reached, it is used as the basis of the Commission's proposal. All procedural requirements of the Administrative Procedure Act (APA) and other applicable statutes continue to apply.

4. When making a determination regarding the suitability of a proceeding for the negotiated rulemaking process, the Commission must consider whether:

(a) There is a need for the rules to be developed;

(b) There are a limited number of identifiable interests that will be significantly affected by the rules;

(c) There is a reasonable likelihood that a committee can be converted with a balanced representation of persons who (1) can adequately represent the identifiable interests and (2) are willing to negotiate in good faith to reach a consensus on the proposed rules;

(d) There is a reasonable likelihood that a committee will reach a consensus on the proposed rules within a fixed period of time;

(e) The negotiated rulemaking procedure will not unreasonably delay the notice of proposed rulemaking and the issuance of final rules;

(f) The agency has adequate resources and is willing to commit such resources, including technical assistance, to the committee, and

(g) The agency will, to the maximum extent possible consistent with the legal obligations of the agency, use the consensus of the committee with respect to the proposed rules as the basis for the rules proposed by the agency for notice and comment. Negotiated Rulemaking Act Sec. 3, 5 U.S.C. Sec. 583(a).

II. Subject and Scope of Rule for Negotiated Rulemaking

5. The Commission proposes that the regulations specifying the requirements for hearing aid compatible telephones in all workplaces, hospitals, certain other health care facilities, prisons, hotels and motels be developed through negotiation. We believe that the selection criteria listed above are met. The suspension of enforcement of the Commission's HAC regulations must be clarified, removed, or modified in a further notice of proposed rulemaking. The parties whose interests are affected are identifiable from comments filed in this proceeding. We believe that these interests can be adequately represented on a committee, and that representatives will act in good faith to reach a consensus on technical rules within a prescribed time. We believe that the negotiated rulemaking process will use public and private resources more efficiently than the submission of additional written comments. We have adequate resources to commit to this endeavor and would use the consensus report of the committee to develop proposed rules.

6. The Commission has identified the following primary issue that should be addressed in the negotiations and resolved in the proposed rules developed by the Committee:

Whether to lift the suspension of enforcement of § 68.112(b) (1), (3), and (5) of the Commission's rules and require that all telephones in all workplaces, hospitals, certain other health care facilities, prisons, hotels and motels be hearing aid compatible by a specific date.

If the Negotiated Rulemaking Committee is able to reach consensus on the primary issue, we ask that it propose specific rules. We ask the Committee to provide an analysis of how the benefits of these proposed regulations outweigh other options. Specifically, we ask the Committee to explain and provide:

—A definition of "telephones provided for emergency use" at the workplace, hotels, motels, and hospital facilities;

—The timeline for implementing any new requirements, including whether establishments with fewer than 20

employees should be given additional time to comply with the requirements;

—The costs and benefits of implementation;

—Any other available data concerning the effects on economic growth expected to result from the implementation of the regulations;

—The impact of its recommendations on access to telecommunications services;

—An analysis of technological alternatives to HAC retrofitting; and

—An analysis of: the general applicability of HAC requirements to cellular telephony; whether telephones in airplanes, trains automobiles and other non-traditional workplaces should be hearing aid compatible; and whether headset telephones should be hearing aid compatible.

Other issues may be included by the parties.

III. Potential Interests and Participants

7. The Commission has identified the following interests as those most likely to be significantly affected by the proposed rules:

(a) Individuals and organizations representing small and large businesses, government agencies, universities, hospitals, hotels, motels, and non-profit institutions;

(b) Equipment manufacturers and common carriers providing telephone service;

(c) Advocates for persons with hearing disabilities.

8. The following have tentatively been identified as potentially affected interests should the Commission proceed with a negotiated rulemaking: the Alexander Graham Bell Association; Utilities Telecommunications Counsel; the North American Telecommunications Association; the Direct Marketing Association; the National Center for Law and Deafness, Gallaudet University; Goodwill Industries of Seattle Washington; Telecommunications for the Deaf, Inc.; the United States Telephone Association; the National Association for the Deaf; Self Help for Hard of Hearing People; Southern New England Telephone Company; GTE Service Corporation; the American Speech-Language-Hearing Association; Maryland Office of People's Counsel; the New York League for the Hard of Hearing; Arizona Counsel for Hearing Impaired; the Association of Colleges and University Telecommunications Administrators; the International Telecommunications Association; the Food Marketing Institute; the American Petroleum Institute; the Tele-Communications Association; the National Retail Federation; the Newspaper Association of America; the National American Wholesale Grocers Association; the Equal Employment Advisory Council; the American Consulting Engineers Council; the New York Clearing House Association; and the Domestic Facilities Division, Common Carrier Bureau, Federal Communications Commission.

IV. Formation of the Negotiating Committee

A. Procedure for Establishing an Advisory Committee

9. Under FACA, an Advisory Committee may be established only after consultation with the General Services Administration (GSA) and the filing of a charter with Congress. The Commission will prepare a charter and initiate the requisite consultation process prior to formation of the Committee and the commencement of negotiations.

B. Participants

10. The number of participants in the group is estimated to be about 20 and should not exceed 25. A greater number of participants could make it difficult to conduct efficient negotiations. Each interest will have the opportunity to be adequately represented, although this does not necessarily mean that each potentially affected entity will have its own representative. Further, we must be satisfied that the group, as a whole, reflects a proper balance and mix of interests. In this respect, we are especially interested in receiving nominations to participate from public interest advocacy groups, user groups, and educators and academics.

11. Entities that will be significantly affected by the proposed rules and that believe that their interests will not be adequately represented by any entity specified in paragraph 8 above, may apply for, or nominate another entity for, membership on the Committee. Each application for nomination must include:

(a) The name of the applicant or nominee and a description of the interests the entity will represent,

(b) Evidence that the applicant or nominee is authorized to represent parties related to the interests the entity proposes to represent,

(c) A written commitment that the applicant or nominee shall actively participate in good faith in the development of the rules under consideration,

(d) The reasons that the entities specified in paragraph 8 do not adequately represent the interests of the entity submitting the application or nomination.

12. If, in response to this *Notice*, any additional entities request membership or representation in the negotiating group, the Commission will determine whether that entity should be added to the group. The Commission will make that decision based on whether the entity would be substantially affected by the rule and whether that entity is already adequately represented in the negotiating group.

C. Agenda

13. If the Commission decides to establish a negotiating committee and its charter is approved, it is anticipated that the Committee's first meeting will take place later this year, at the Commission's offices, in Washington, DC, at a room, date, and time that will be announced. At this initial meeting, the Committee will complete action on all procedural matters and establish a target date for submission of its recommendations. We expect that the target date would be no later than 45 days from the initial meeting of the Committee. We anticipate adoption of a Further Notice of Proposed Rulemaking no later than 60 days after the submission of the Committee's recommendations.

V. Negotiation Procedures

14. The following procedures and guidelines will apply to the Committee, if formed. These procedures may be modified, however, after reviewing the comments received in response to this *Notice* or during the negotiation process.

A. Facilitator

15. The Commission will nominate a person to serve as a neutral facilitator for the negotiations of the Committee, subject to the approval of the Committee by consensus. The facilitator will not be involved in the substantive development of the regulations. The facilitator's roles are to: (1) Chair negotiating sessions; (2) help the negotiation process run smoothly; (3) assist participants in defining and reaching a consensus; and (4) manage record-keeping and minute-keeping.

B. Good Faith Negotiations

16. Since participants must be willing to negotiate in good faith, each organization—including the Commission—must designate a qualified individual to represent its interests. Linda B. Dubroof, Acting Branch Chief, Domestic Facilities Division, Common Carrier Bureau, will be the Commission's representative.

C. Meetings and Compensation

17. Meetings will be held in the Washington, DC area at the convenience of the Committee. The Commission, if requested, will provide the facilities needed to conduct the meetings, and will provide any necessary technical support. Private sector members of the Committee will serve without government compensation or reimbursement of expenses. Private sector members will not be special government employees for any purposes whatsoever.

D. Committee Procedures

18. Under the general guidance and direction of the facilitator, and subject to any applicable legal requirements, the members will establish the procedures for committee meetings.

E. Consensus

19. The goal of the Committee is consensus. The Negotiated Rulemaking Act defines consensus as unanimous concurrence among the represented interests, although the Act permits the Committee to agree to another specified definition. In the event the Committee is unable to reach a consensus, the Committee may include in a report any other information, recommendations, or materials that the Committee considers appropriate, and any Committee member may include as an addendum to the report additional information, recommendations, or materials. Parties to the negotiation may withdraw at any time. If this happens, the remaining Committee members and the Commission will evaluate whether the Committee should continue.

F. Record of Meetings

20. Pursuant to FACA, the Committee will keep a record of all committee meetings. This record will be placed in the public docket for this rulemaking (CC Docket No. 87–124). The Commission will announce committee meetings in the **Federal Register**. These meetings will be open to the public.

VI. Conclusion

21. The Commission requests public comment on whether: (1) It should establish a Federal Advisory Committee, (2) it has properly identified the interests that are significantly affected by the key issues listed above, (3) the suggested committee membership reflects a balanced representation of these interests, and (4) regulatory negotiation is appropriate for this rulemaking.

22. Pursuant to the applicable procedures set forth in Section 4(c) of the Negotiated Rulemaking Act of 1990, 5 U.S.C. Section 584(c), interested parties may file comments and nominations for Committee membership on or before thirty days from **Federal Register** publication of this notice. Comments and/or nominations should be sent to the Office of the Secretary, CC Docket No. 87–124, Federal Communications Commission, Washington, DC 20554. Comments and nominations will be available for public inspection during regular business hours in the Commission's Reference Center, Room 239, 1919 M St., NW., Washington, DC.

23. For further information pertaining to the establishment of the negotiation committee and associated matters, contact John Walker, Common Carrier Bureau, 2025 M Street, NW., Washington, DC 20554, (202) 634–1820 or (202) 632–0484 (TTY).

24. Action by the Commission October 31, 1994, by Public Notice (FCC 94–280, released November 7, 1994) by Chairman Hundt, Commissioners Quello, Barrett, Ness, and Chong.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 94–28518 Filed 11–22–94; 8:45 am]

BILLING CODE 6712–01–M

Notices

Federal Register
Vol. 59, No. 225
Wednesday, November 23, 1994

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Alaska Region; Legal Notices Required Under 36 CFR Part 215

AGENCY: Forest Service, USDA.
ACTION: Notice.

SUMMARY: In accordance with 36 CFR Part 215, Deciding Officers in the Alaska Region will publish Notices of Proposed Actions and Notices of Decisions Subject to Administrative Appeal in the Legal Notice Section of the newspapers listed in the Supplementary Information Section of this Notice. As provided in 36 CFR 215.5, such notices shall constitute legal evidence that the agency has given timely and constructive Notice of Proposed Actions and Notice of Decisions Subject to Administrative Appeal. Newspaper publication of Notices of Proposed Actions and Notices of Decisions is in addition to direct notice to persons who have requested notice in writing and to persons known to be interested in or affected by a specific proposal or decision.

DATES: Use of these papers for purposes of publishing Legal Notices of Proposed Actions and Notices of Decisions Subject to Administrative Appeal shall begin November 1, 1994.

FOR FURTHER INFORMATION CONTACT: Cherie Shelley, Regional Appeals Coordinator, Alaska Region, USDA Forest Service, EPB, P.O. Box 21628, Juneau, Alaska 99802, Telephone (907) 586–8855.

SUPPLEMENTARY INFORMATION: Deciding Officers in the Alaska Region will give Legal Notices of Proposed Actions and Notices of Decisions Subject to Administrative Appeal in the following newspapers which are listed by Forest Service administrative unit. Where more than one newspaper is listed for any unit, the first newspaper listed is the primary newspaper which shall be used to constitute legal evidence that the agency has given timely and constructive Notice of Proposed Actions and Notice of Decisions Subject to Administrative Appeal. As provided at 36 CFR 215.6, the timeframe for public comment on proposed actions shall be based on the date of publication of a Notice of Proposed Action in the primary newspaper. As provided at 36 CFR 215.13, the timeframe for appeal shall be based on the date of publication of a Notice of Decision in the primary newspaper.

Decisions by the Regional Forester

"Juneau Empire," published daily except Saturday and official holidays in Juneau, Alaska, for decisions affecting National Forest System lands in the State of Alaska and for any decision of Region-wide impact.
"Anchorage Daily News," published daily in Anchorage, Alaska, for decisions affecting National Forest System lands in the State of Alaska and for any decisions of Region-wide impact.

Decisions by the Chugach Forest Supervisor and the Glacier District Ranger, Chugach National Forest

"Anchorage Daily News," published daily in Anchorage, Alaska.

Decisions by the Cordova District Ranger, Chugach National Forest

"Anchorage Daily News," published daily in Anchorage, Alaska.
"Cordova Times," published weekly in Cordova, Alaska.

Decisions by the Seward District Ranger, Chugach National Forest

"Anchorage Daily News," published daily in Anchorage, Alaska.
"Seward Phoenix Log," published weekly in Seward, Alaska.
"Peninsula Clairion," published daily except Saturday, Sunday, and official holidays in Kenai, Alaska.

Decisions by the Chatham Area Forest Supervisor, the Yakutat District Ranger, the Hoonah District Ranger, the Juneau District Ranger, and the Admiralty National Monument Ranger, Chatham Area of the Tongass National Forest

"Juneau Empire," published daily except Saturday and official holidays in Juneau, Alaska.

Decisions by the Sitka District Manager, Chatham Area of the Tongass National Forest

"Daily Sitka Sentinel," published daily except Saturday, Sunday, and official holidays in Sitka, Alaska.

Decisions by all Deciding Officers of the Ketchikan Area of the Tongass National Forest

"Ketchikan Daily News," published daily except Sunday and official holidays in Ketchikan, Alaska.

Decisions by the Stikine Area Forest Supervisor and the Petersburg District Ranger, Stikine Area of the Tongass National Forest

"Petersburg Pilot," published weekly in Petersburg, Alaska.

Decisions by the Wrangell District Ranger, Stikine Area of the Tongass National Forest

"Wrangell Sentinel," published weekly in Wrangell, Alaska.

Dated: November 7, 1994.

Phil Janik,

Regional Forester.

[FR Doc. 94–28867 Filed 11–22–94; 8:45 am]

BILLING CODE 3410–11–M

Soil Conservation Service EIS; Cabin Branch Watershed, SC

AGENCY: Soil Conservation Service.
ACTION: Notice of a finding of no significant impact.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Regulations (40 CFR Part 1500); and the Soil Conservation Service Regulations (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement (EIS) is not being prepared for the Cabin Branch Watershed, Richland County, South Carolina.

FOR FURTHER INFORMATION CONTACT: Mr. Jose J. Acevedo, Deputy State Conservationist, Soil Conservation Service, 1835 Assembly Street, room 950, Columbia, South Carolina 29201, telephone (803) 765–5681.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Mr. Jose J. Acevedo, Deputy State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The project purposes are to reduce flooding and improve flow conditions

on 6.0 miles of new and/or renovated channels to facilitate the removal of stormwater in the Hopkins Community.

The Notice of a Finding Of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various Federal, State, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Eddie L. Kephart, Water Resources Coordinator, at the above address.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register**.

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.904, Watershed Protection and Flood Prevention, and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials.)

Jose J. Acevedo,

Deputy State Conservationist.

[FR Doc. 94–28868 Filed 11–22–94; 8:45 am]

BILLING CODE 3410–16–M

DEPARTMENT OF COMMERCE

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of the Census.

Title: Survey of Income and Program Participation – 1993 Panel Wave 8.

Agency Approval Number: 0608–0759.

Type of Request: Revision of a currently approved collection.

Burden: 63,000 hours.

Number of Respondents: 42,000 hours.

Avg Hours Per Response: 30 minutes.

Needs and Uses: The Survey of Income and Program Participation (SIPP) is a longitudinal demographic survey in which the Census Bureau interviews sample households in waves occurring every 4 months over about a 2½ year period. The survey is molded around a central "core" of labor force and income questions that remain fixed during each wave of a panel. The core is periodically supplemented with questions designed to answer specific needs. These supplemental questions are referred to as "topical modules." The topical modules for the 1993 Panel Wave 8 interview collectively are called the "Annual Round-Up" topical modules. The individual components are: 1) Annual Income and Retirement Accounts, 2) Taxes, and 3) School Enrollment and Financing. Wave 8 interviews will be conducted from June through September 1995. SIPP data on income distribution and changes over time in status and participation in welfare and transfer programs are used by economic policymakers, the Congress, state and local governments, and Federal agencies that administer these programs to support policy and program planning.

Affected Public: Individuals or households.

Frequency: Once during the panel.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Maria Gonzalez, (202) 395–7313.

Copies of the above information collection proposal can be obtained by calling or writing Gerald Taché, DOC Forms Clearance Officer, (202) 482–3271, Department of Commerce, room 5312, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Maria Gonzalez, OMB Desk Officer, room 10201, New Executive Office Building, Washington, DC 20503.

Dated: November 17, 1994.

Gerald Taché,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 94–28887 Filed 11–22–94; 8:45 am]

BILLING CODE 3510–07–F

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Economic Development Administration.

Title: Current and Projected Employee Data.

Agency Approval Number: 0610–0003.

Type of Request: Extension of a currently approved collection.

Burden: 600 hours.

Number of Respondents: 800 hours.

Avg Hours Per Response: .75 hours.

Needs and Uses: This report is needed to assist in determining compliance of entities assisted by EDA with Title VI of the Civil Rights Act of 1964 and implementing Departmental and Agency regulations. Those entities creating or saving less than 15 jobs as a result of EDA assistance are not required to complete this report.

Affected Public: State or local governments, businesses or other for-profit institutions, and non-profit institutions.

Frequency: On occasion and annually.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: Don Arbuckle, (202) 395–7304.

Copies of the above information collection proposal can be obtained by calling or writing Gerald Taché, DOC Forms Clearance Officer, (202) 482–3271, Department of Commerce, room 5312, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Don Arbuckle, OMB Desk Officer, room 10202, New Executive Office Building, Washington, DC 20503.

Dated: November 17, 1994.

Gerald Taché,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 94–28888 Filed 11–22–94; 8:45 am]

BILLING CODE 3510–CW–F

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: GLOBE Registration and Application.

Agency Form Number: None Assigned.

OMB Approval Number: None.

Type of Request: New Collection.

Burden: 4,500 hours.

Number of Respondents: 5,000.

Avg Hours Per Response: 30 minutes for Registration form and one hour for an assistance request.

Needs and Uses: The Global Learning and Observations to Benefit the Environment (GLOBE) program is a hands-on-program that joins students, educators, and scientists in studying the global environment. Schools wishing to participate in the program must submit a registration form. Schools needing financial assistance must submit an application form.

Affected Public: State or local governments.

Frequency: One-time per school.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: Don Arbuckle, (202) 395–7340.

Copies of the above information collection proposal can be obtained by calling or writing Gerald Tache, DOC Forms Clearance Officer, (202) 482-3271, Department of Commerce, Room 5327, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Written comments and recommendations for the proposed information collection should be sent to Don Arbuckle, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, D.C. 20503.

Dated: November 17, 1994.

Gerald Tache,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 94–28892 Filed 11–22–94; 8:45 am]

BILLING CODE 3510–CW–F

International Trade Administration, Commerce.

Export Trade Certificate of Review

ACTION: Notice of Issuance of an Amended Export Trade Certificate of Review, Application No. 92–3A001.

SUMMARY: The Department of Commerce has issued an amendment to the Export Trade Certificate of Review granted to the Aerospace Industries Association of America, Inc. ("AIA") on April 10, 1992. Notice of issuance of the Certificate was published in the **Federal Register** on April 17, 1992 (57 FR 13707).

FOR FURTHER INFORMATION CONTACT: W. Dawn Busby, Director, Office of Export Trading Company Affairs, International Trade Administration, (202) 482–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR Ch. III Part 325 (1994).

The Office of Export Trading Company Affairs is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Department of Commerce to publish a summary of a Certificate in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Amended Certificate

Export Trade Certificate of Review No. 92–00001 was issued to the Aerospace Industries Association of America, Inc. ("AIA") on April 10, 1992 (57 FR 13707, April 17, 1992), and previously amended on September 8, 1992 (57 FR 41920, September 14, 1992) and on October 8, 1993 (58 FR 53711, October 18, 1993).

AIA's Export Trade Certificate of Review has been amended to:

1. Add the following companies as "Members" within the meaning of section 325.2(1) of the Regulations (15 CFR 325.2 (1)): Dynamic Engineering Incorporated, Newport News, VA; Ceridian Corporation, Minneapolis, MN, for the activities of its division Computing Devices International, Bloomington, MN; AAI Corporation, Hunt Valley, MD; and Teleflex Inc., Plymouth Meeting, PA.;

2. Delete the following companies as "Members" of the Certificate: BASF Structural Materials, Charlotte, NC (Controlling Entity: BASF Corporation, Parsippany, NJ); Bechtel National, Inc., San Francisco, CA (Controlling Entity: Bechtel Group, Inc., San Francisco, CA); Best Foam Fabricators, Inc., Chicago, IL; CTA Incorporated, Rockville, MD; Edwards Aerospace, Inc., Irving, TX (Controlling Entity: Edwards Technology, Inc., Irving, TX); IBM Corporation, Armonk, NY; Ontario Corporation, Muncie, IN; Precision Castparts Corporation, Portland, OR; and Smiths Industries Aerospace and Defense, Grand Rapids, MI (Controlling Entity: Smith Industries PLC, ENGLAND NW1 18DS); and

3. Change the listing of the following current "Members" as follows: change the name of Rohr Industries, Inc. to Rohr, Inc.; and consolidate the listings for the Grumman Corporation and the Northrop Corporation into the Northrop Grumman Corporation.

A copy of the amended certificate will be kept in the International Trade Administration's Freedom of Information Records Inspection Facility, Room 4102, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230.

Dated: November 17, 1994.

W. Dawn Busby,

Director, Office of Export Trading Company Affairs.

[FR Doc. 94–28893 Filed 11–22–94; 8:45 am]

BILLING CODE 3510–DR–P

National Institute of Standards and Technology

[Docket No. 94048–4248]

Standard Generalized Mark-Up Language Editor Project

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of collaboration opportunity.

SUMMARY: The National Institute of Standards and Technology (NIST) through this notice is inviting potential collaborators to work with NIST in the development of certain computer programs in support of International Standards Organizations (ISO) Standard 10303, known as the Standard for the Exchange of Product model data, or STEP. These computer programs are known collectively as the "Application Protocol Development Environment", or APDE. The focus of the research for which NIST seeks collaborators would be the customization of a computer program, or "editor" that uses the Standard Generalized Mark-up Language (SGML) to create STEP documents in an automated environment. The editor would become one of the component parts of the APDE. NIST will work with a party who has already developed SGML editors to customize their software for use in the STEP community.

DATES: Expressions of interest from software developers or suppliers that meet the requirements set out in this notice should contact NIST at the address shown below no later than December 23, 1994.

ADDRESSES: Metrology Building, room A–127, National Institute of Standards and Technology, Gaithersburg, MD 20899.

FOR FURTHER INFORMATION CONTACT: Ms. Mary Mitchell, (301) 975–3538, fax: (301) 869–0917, E–Mail: mitchell@cme.nist.gov

SUPPLEMENTARY INFORMATION: The National Institute of Standards and Technology (NIST) is developing the Application Protocol Development Environment (APDE) is support of the emerging standard ISO 10303, known as the Standard for the Exchange of Product model data (STEP). The ADPE will be set of integrated software tools used to accelerate the development of quality STEP Application Protocols.

The APDE will include an automated environment for creating STEP documents using the Standard Generalized Mark-up Language (SGML). One component of this SGML environment will be an SGML editor

that can be customized by means of either an Application Programmer Interface (API) or scripting language.

NIST plans to collaborate with only one software supplier in the development of this editor. This collaboration will involve NIST customization of the software supplier's generic SGML editor for the STEP community.

The requirements for the generic SGML editor include SGML-aware editing capabilities (structure-based searching, insertion of SGML elements and entities, editing SGML attribute values, structure-enforced editing); Word processing capabilities (formatted display, cut, paste, copy, delete, etc.); Inherent customization capabilities (API or scripting language for developing customizations, standard editor-accessible customization options); Software integration capabilities (open architecture, scaleable and extensible); Multiple platform availability (unix workstation using X Windows, IBM PC using Microsoft Windows, MacIntosh-desirable, but not required); and Available at reduced cost to both end users and developers.

Interested parties should note that one SGML supplier has already offered to collaborate with NIST in the form of a Cooperative Research and Development Agreement in this endeavor. This includes an offer by them to both donate their SGML editor and scripting language to NIST at no cost and to sell their product to the STEP community at a reduced cost. The scripting language included with their editor would allow NIST to provide the editor and customizations at no additional charge.

Dated: November 18, 1994

Samue Kramer,

Associate Director.

[FR Doc. 94–28943 Filed 11–22–94; 8:45 am]

BILLING CODE 3510–13–M

Malcolm Baldrige National Quality Award's Board of Overseers

AGENCY: National Institute of Standards and Technology, DOC.

ACTION: Notice of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. app. 2, notice is hereby given that there will be a meeting of the Board of Overseers of the Malcolm Baldrige National Quality Award on Sunday, December 4, 1994, from 1:00 p.m. to 6:00 p.m. This meeting replaces the meeting originally scheduled on Monday, November 14, 1994, rescheduled because of last minute schedule changes by some of the Overseers. The Board of Overseers consists of eight members prominent in the field of quality management and appointed by the Secretary of Commerce, assembled to advise the Secretary of Commerce on the conduct of the Baldrige Award. The purpose of the meeting on December 4, 1994, will be for the Board of Overseers to receive and then discuss reports from the National Institute of Standards and Technology with the chairman of the Judges Panel of the Malcolm Baldrige National Quality Award. These reports will cover the following topics: Overview of the 1994 award program; discussion of the Overseers survey of CEO's; discussions of plans for the 1995 award, develop recommendations and report same to The Director of the National Institute of Standards and Technology.

DATES: The meeting will convene on Sunday, December 4, 1994 at 1:00 p.m., and adjourn at 6:00 p.m. on December 4, 1994.

ADDRESSES: The meeting will be held at the National Alliance of Business, 1201 New York Avenue NW, Suite 700, Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Dr. Curt W. Reimann, Director for Quality Programs, National Institute of Standards and Technology, Gaithersburg, Maryland 20899, telephone number (301) 975–2036.

SUPPLEMENTARY INFORMATION: While it is Departmental policy to hold all advisory committee meetings during normal working hours, the Department has made an exception to this general policy since this meeting was rescheduled due to last minute emergencies which included grave illness and hospitalization of the wife of one of the Overseers and emergency hospitalization of the Chairman of the Board. These emergencies, in addition to the death of one Board member several weeks earlier and prior commitment on the part of one member, reduced the attendance enough to determine that full conduct of the business of the Board would require that the meeting be rescheduled. The only available date for the meeting, that would accommodate the schedules of the Overseers and allow presentation of a report to the Secretary of Commerce on December 5, was Sunday December 4, 1994.

Because of the unusual timing, this advisory committee has taken extraordinary steps to insure access to this meeting by the public. Anyone wishing to attend should register with the guard on duty in the lobby at 1201 New York Avenue, Washington, D.C., who will then give directions to the meeting room.

Dated: November 18, 1994.

Samuel Kramer,

Associate Director.

[FR Doc. 94–28941 Filed 11–22–94; 8:45 am]

BILLING CODE 3510–03–M

OSE Implementors' Workshop (OIW); Notice of 1995 Meeting Dates

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice.

SUMMARY: The NIST announces four (4) workshop sessions to reach implementor agreements for Open System Environment (OSE) Information Technology Standards.

DATES: The 1995 meeting dates for the workshops have been established and are as follows:

March 14, 15, 16, 1995

June 13, 14, 15, 1995

September 12, 13, 14, 1995

December 5, 6, 7, 1995

The meetings are sponsored by NIST and the IEEE Computer Society and will be held at NIST in Gaithersburg, Maryland.

ADDRESSES: To register for the workshops, companies may contact: The OSE Implementor's Workshop Secretariat at the National Institute of Standards and Technology, Building 225, Room B–266, Gaithersburg, MD 20899, Telephone: (301) 975–3664. The registration request must name the company representative(s) and specify the business address and telephone number for each participant.

FOR FURTHER INFORMATION CONTACT: For questions about the technical program, contact Albert T. Landberg (301) 975–2245.

SUPPLEMENTARY INFORMATION: The primary activities of these quarterly workshops include continuing work on Open System Environment (OSE) and the National Information Infrastructure (NII) application interfaces. A registration fee is charged for Workshop attendance. Participants are expected to make their own travel arrangements and accommodations. NIST reserves the right to cancel any part of the workshops.

Dated: November 17, 1994.

Samuel Kramer,

Associate Director.

[FR Doc. 94–28942 Filed 11–22–94; 8:45 am]

BILLING CODE 3510–CN–M

National Oceanic and Atmospheric Administration

[Docket No. 941122-4322]

RIN 0648-ZA12

Global Learning and Observations to Benefit the Environment (GLOBE)

AGENCY: National Oceanic and Atmospheric Administration, COMMERCE (DOC).

ACTION: Notice of program and availability of Federal assistance.

SUMMARY: This is an invitation for U.S. K–12 schools to participate in a new international environmental science and education program known as Global Learning and Observations to Benefit the Environment (GLOBE). U.S. schools can participate in the GLOBE Program if they meet the "basic requirements" described below by simply completing the registration form included below. If a U.S. school does not have the resources necessary to meet these "basic requirements," it can apply for Federal assistance to enable it to participate in the GLOBE Program using the Application for Federal Assistance included below. GLOBE is managed by an interagency team that includes the National Oceanic and Atmospheric Administration (NOAA), the National Aeronautics and Space Administration (NASA), the National Science Foundation (NSF), the Environmental Protection Agency (EPA), and the Departments of Education and State. GLOBE leadership also includes the White House Office on Environmental Policy and the Office of Science and Technology Policy. NOAA is the lead agency for GLOBE. As lead agency, NOAA invites U.S. K–12 schools to participate in the GLOBE Program as described below.

The GLOBE Program is a hands-on program that joins students, educators, and scientists from around the world in studying the global environment. GLOBE will be a worldwide network of students who will work under the guidance of GLOBE-trained teachers to make environmental observations at or near their schools, report their data to a GLOBE processing facility, receive and use global images created from their data, and study environmental topics in their classrooms.

DATES: Requests for Federal assistance must be received by December 28, 1994.

ADDRESSES: Requests for the registration form or the Application for Federal Assistance form and completed forms should be sent by mail to Thomas N. Pyke, Jr., Director, The GLOBE Program, 744 Jackson Place, N.W., Washington, D.C. 20503 or delivered by express or courier service to Director, The GLOBE Program, The White House, New Executive Office Building, 725 17th Street, N.W., Room G–1, Washington, D.C. 20006. Facsimile copies are not acceptable.

FOR FURTHER INFORMATION CONTACT: Interested applicants should contact Thomas N. Pyke, Jr., Director, The GLOBE Program, at (202) 395–6500.

SUPPLEMENTARY INFORMATION:

I. Introduction

1. Program Description

GLOBE is a hands-on, school-based program that will:

—Enhance environmental awareness of individuals throughout the world,
—Enable students to make environmental observations that will contribute to improving the health of planet Earth,
—Give students the opportunity to work with world class scientists, collaborating together through a worldwide network,
—Involve students, teachers, and scientists in sharing information about the global environment,
—Enrich and supplement existing school curricula in science and mathematics, and

Help all students reach higher standards in science and mathematics.

The program consists of a worldwide network of students who will make environmental observations at or near their schools under the guidance of GLOBE-trained teachers. The students will report their data to a GLOBE processing center, receive and use global images created from their data, and study environmental topics in their classrooms. The data acquired by students will be used worldwide by environmental scientists in their research to improve our understanding of the global environment. The GLOBE concept was announced by Vice President Al Gore on Earth Day, April 22, 1994. Since then, over ninety nations have expressed interest in joining the U.S. in the GLOBE Program. GLOBE will begin operation on the 25th Earth Day, April 22, 1995, and schools in the U.S. and throughout the world are invited to join in this exciting new venture.

"Basic Requirements"

A school satisfies the "basic requirements" to become a GLOBE school if the school agrees to :

—Have its students acquire environmental data using scientific instruments at their schools,
—Have its students transmit these data to a GLOBE processing center as often as required for each measurement,
—Have its students study the global environmental images that will be generated based on GLOBE data taken by students around the world,
—Have its students participate in GLOBE guided by one or more teachers trained through the GLOBE Program, who will use GLOBE-provided educational materials,
—Send at least one teacher to a GLOBE-provided 3-day training workshop at a location in the school's general part of the country,
—Have the necessary GLOBE scientific measurement instruments, as identified below, for use by students, and
—Have a suitable school computer configuration, as described below, to be used at least 20% of each school day to support participation in GLOBE, i.e., to be used for data entry and transmission to a GLOBE processing center and for viewing of global environmental images and related information generated from GLOBE data by a GLOBE processing center.

Scientific Measurement Instruments

GLOBE environmental measurements are in the following study areas: Atmosphere/Climate, Hydrology/Water Chemistry, and Biology/Geology.

The GLOBE measurements to be made initially by students in grades K–5 are:

Atmosphere/Climate: Maximum and minimum air temperature, precipitation, and cloud cover
Hydrology/Water: Water temperature, pH of precipitation
Biology/Geology: Biometrics, species identification, and land cover

The scientific instruments needed to make these measurements are a max/min thermometer, a rain gauge, a tape measure, a clinometer, Litmus paper, and a "cloud kit" and simple species identification keys to be provided as part of the GLOBE educational materials. The functional and performance specifications for these GLOBE scientific instruments will be provided to each school that registers to participate in the GLOBE Program. The total cost of these scientific instruments, if they are not already available at the school, is estimated to be between $150 and $250. After the initial year of GLOBE operation, additional measurements will be added at the K–5 level, such as measurement of barometric pressure and soil moisture. The additional cost of the instruments necessary at that time to make these

additional measurements is estimated to be about $100.

The measurements to be made by students in grades 6–12, in addition to all of the above measurements made by K–5 students, are:

Hydrology/Water: pH of precipitation taken with more advanced measurement devices, soil moisture

Biology/Geology: phenology (seasonal change), location of the site at which physical measurements are taken

The scientific instruments necessary to make these measurements include all of the above instruments for grades K–5, in addition to a digital readout pH pen for grades 6–8 and a research quality pH meter for grades 9–12, an oven, a balance, and a camera with film. The functional and performance specifications for these GLOBE scientific instruments will be provided to each school that registers to participate in the GLOBE Program. A Global Positioning System (GPS) receiver, to be used to determine the location of the site at which physical measurements are taken, will be made available for use at the school measurement sites by the GLOBE Program, as needed. The total cost of these scientific instruments, if they are not already available at the school, is estimated to be between $300 and $400 for grades 6–8 and between $800 and $1000 for grades 9–12. After the initial year of GLOBE operation, additional measurements will be added at the 6–12 level, such as measurement of dew point, soil temperature, and of trace gases. The additional cost of the instruments necessary at that time to make these additional measurements is estimated to be between $300 and $400 for grades 6–8 and between $300 and $500 for grades 9–12.

School Computer Configuration

Either an IBM-compatible PC or an Apple Macintosh computer can be used:

An IBM-compatible PC with at least a 386, 20 Mhz processor, 4 MB of RAM memory, and 60 MB of available hard disk. It must have either a direct Internet connection or a dial-up capability using a 14.4 kbps modem, preferably employing V.42 bis data compression, that is now being used to access the Internet on a dial-in basis or can be used to do so if the school is provided with a suitable 800 telephone number.

An Apple Macintosh computer with at least a 68030, 20 Mhz processor, 4 MB of RAM memory, and 60 MB of available hard disk. It must have either a direct Internet connection or a dial-up capability using a 14.4 kbps modem, preferably employing V.42 bis data compression, that is now being used to access the Internet on a dial-in basis or can be used to do so if the school is provided with a suitable 800 telephone number.

Registering as a GLOBE School

Schools that meet the "basic requirements" stated above are invited to complete the registration form included below. The form must be signed by the school's principal, its designated GLOBE lead teacher, and by an official authorized to make the necessary certification on behalf of the school. The form should be mailed to The GLOBE Program, 744 Jackson Place, Washington, D.C. 20503.

For each registered school, the Federal Government will provide:

—Daily access through the Internet to global environmental images based on the measurement data taken by GLOBE students around the world and a broad range of other information relevant to the study of the global environment,

—An opportunity for students and teachers to work interactively through the Internet with world class scientists, collaborating in the study of the environment,

—An opportunity for students, teachers, and scientists to share information about the global environment through the Internet with each other,

—Training for one teacher (the GLOBE lead teacher for the school) at a 3-day workshop to be held at a location in the school's general part of the country (but not including the cost of travel or per diem for the teacher to attend the training or the cost of a substitute teacher if one is necessary),

—A set of GLOBE educational materials for use by teachers and students in the school to enrich and supplement existing school curricula,

—If the school is not already connected to the Internet, connectivity will be provided to the Internet through a dial-up telephone connection to an 800 number,

—Access to GLOBE school computer software for use of the World Wide Web information access system through the Internet, if the school does not already have software that can be used for this purpose (This is the software necessary to transmit GLOBE data and access GLOBE global environmental visualizations and other information.), and

—Dial-up telephone access to a GLOBE help desk to an 800 number.

Teacher training will be available for some GLOBE lead teachers for 3-day sessions offered during the period February through May 1995. Training for additional GLOBE lead teachers will be available from June through August 1995. It is expected that only a relatively small percentage of initial GLOBE lead teachers will be able to be trained during the February-May period, and each school's indication for when its GLOBE lead teacher would prefer to participate in training is requested on the registration form.

GLOBE will begin operation on April 22, 1995. Schools that initially register can expect to begin their involvement on a phased-in basis beginning as early as April, but, in some cases, not beginning until later in 1995. Schools for which registration forms are received by the GLOBE Program earliest can generally expect to receive training for their GLOBE lead teachers at an early date, and thus begin GLOBE participation earlier in the year, subject to the magnitude of response to this invitation and the overall process for scheduling teacher training workshops across the country.

Federal Assistance

Some Federal assistance will be available on a competitive basis to assist selected domestic schools in meeting some of these "basic requirements." GLOBE encourages schools which do not meet all of the "basic requirements" identified above to complete the Application for Federal Assistance form included below to compete to acquire from the Federal Government the necessary resources to enable the school to participate in the GLOBE Program. It is expected that available U.S. Government resources to help individual schools to participate in GLOBE will be limited compared to the total need. Schools desiring to participate in GLOBE are encouraged to seek alternative resources. However, no matching is required.

The application form for applying for Federal assistance under this solicitation is contained within this announcement. Schools applying for Federal assistance may be required to complete additional Federal assistance forms as required by DOC.

2. Authority and Type of Funding Instrument

GLOBE may enter into Joint Project Agreements (JPA), contracts and/or cooperative agreements to carry out the objectives of this program. NOAA intends to use JPAs pursuant to 15 U.S.C. 1525 with those educational institutions that do not require funds to acquire the resources necessary to meet the "basic requirements" identified

above. The duration of the agreements will be for three year periods.

For those educational institutions that require and are selected to receive Federal assistance, NOAA intends to use cooperative agreements pursuant to 15 U.S.C. 1540 to assist educational institutions that are not profit making entities. Procurement contracts may be used to fund for-profit educational organizations that may need resources for the "basic requirements" to participate in the GLOBE Program. NOAA will determine the appropriate funding instrument to use for each applicant in accordance with the Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6301–6308.

3. Catalog of Federal Domestic Assistance

CFDA No. 11.449, Independent Education and Science Projects and Programs.

4. Funding Availability

Funds appropriated for use by the NOAA in support of the GLOBE Program, together with GLOBE funding transferred to NOAA from NASA and EPA, will be employed to make awards in response to this solicitation.

II. Program Requirements for Participation and Funding

The selection of schools to receive Federal assistance to enable them to participate in the GLOBE Program will be guided by the program's goals: (1) To enhance environmental awareness of individuals throughout the world, (2) to increase scientific understanding of the Earth, and (3) to help all students reach higher standards in science and mathematics.

The following general rating factors that will be considered in the selection of schools that will receive Federal assistance as a result of this solicitation:

- Schools will be selected so as to achieve geographic and socio-economic diversity in the participation in the GLOBE Program, with an objective of being inclusive in the opportunity for the Nation's young people to participate.
- Schools will be selected so as to provide coverage of the United States where the current availability of the kinds of environmental data to be acquired by schools participating in GLOBE is relatively sparse, and where a significant contribution to global environmental research would be made by having GLOBE schools located there.
- Schools will be selected that intend to make GLOBE measurements and transmit the data for GLOBE processing as often as necessary for each measurement for at least the next 3 years.

The following programmatic rating factors will be rated and given equal weight:

- Schools will receive credit if they propose to involve a large percentage of their students in GLOBE.
- Schools will receive credit if they propose to arrange to have students make GLOBE measurements on days in addition to regular school days.
- Schools will receive credit if they are part of or plan to collaborate in GLOBE with other nearby participating schools, where this cluster of schools includes one or more proposed elementary schools that feed into a proposed intermediate school that feeds into a proposed high school.
- Schools will receive credit if they propose to involve their local community in the school's GLOBE activities.
- Schools will receive credit if they propose to build on the schools' participation in existing environmental science or related education programs that have some of the characteristics of GLOBE.
- Schools will receive credit if they require partial rather than full Federal Government support of the resources necessary to participate in GLOBE, because they already have part of the required "infrastructure," e.g. a suitably configured PC or Macintosh computer, a connection to the Internet, and all or some of the required scientific instruments.
- Schools will receive credit for "infrastructure" if a school does not yet have, but is willing to commit to obtain, needed resources from alternative sources as a form of "matching" the resources being requested.

3.0 Selection Procedures

GLOBE will convene an interagency review team that includes NOAA, NASA, NSF, EPA, and the Department of Education. The review team will rate the applications, and consider other relevant information available to the Government about each school, in accordance with the GLOBE Program goals and factors identified above. After the applications have been evaluated, the review team will develop recommendations for selection. The recommendations will be submitted to the GLOBE Director, who will determine which applicants will be funded by NOAA or other Federal organizations, and that the applicants selected are those that best meet the goals of the GLOBE program.

The exact amount of assistance or Government resources awarded to an applicant will be determined in pre-award negotiations between the applicant and GLOBE Program representatives. All applicants will be notified of their selection or non-selection. Unsuccessful applicants will be encouraged to seek alternative resources that will enable them to participate in GLOBE.

Schools that are selected to receive Federal assistance to make possible their participation in GLOBE will also receive the same four kinds of Government support listed above for schools that do not need assistance and are simply registering to participate.

At any given time, especially as the GLOBE Program begins during 1995, there may be a constraint on the rate at which GLOBE teacher training and educational materials can be made available, and in which new GLOBE schools can be supported by the GLOBE processing center(s) and required network connections. Every reasonable effort will be made to respond in a timely way to the expected heavy demand, but schools should expect to become "operational" GLOBE schools on a phased-in basis over several months, beginning in March 1995.

III. Other Requirements

1. Federal Policies and Procedures

Recipients and subrecipients are subject to all Federal laws and Federal and DOC policies, regulations, and procedures applicable to Federal financial assistance awards.

2. Past Performance

Unsatisfactory performance under prior Federal awards may result in an application not being considered for funding.

3. Pre-Award Activities

If applicants incur any costs prior to an award being made, they do so solely at their own risk of not being reimbursed by the Government. Notwithstanding any verbal or written assurance that may have been received, there is no obligation on the part of DOC to cover pre-award costs.

4. No Obligation for Future Funding

If an application is selected for funding, DOC has no obligation to provide any additional future funding in connection with that award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of DOC.

5. Delinquent Federal Debts

No award of Federal assistance shall be made to an applicant who has an

outstanding delinquent Federal debt until either:

i. The delinquent account is paid in full,

ii. A negotiated repayment schedule is established and at least one payment is received, or

iii. Other arrangements satisfactory to DOC are made.

6. Name Check Review

All non-profit and for-profit applicants are subject to a name check review process. Name checks are intended to reveal if any key individuals associated with the applicant have been convicted of or are presently facing criminal charges such as fraud, theft, perjury, or other matters which significantly reflect on the applicant's management honesty or financial integrity.

7. Primary Applicant Certifications

All primary applicants must submit a completed Form CD–511, "Certifications Regarding Debarment, Suspension and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying," and the following explanations are hereby provided:

i. Nonprocurement Debarment and Suspension. Prospective participants (as defined at 15 CFR part 26, section 105) are subject to 15 CFR part 26, "Nonprocurement Debarment and Suspension" and the related section of the certification form prescribed above applies;

ii. Drug-Free Workplace. Grantees (as defined at 15 CFR part 28, section 605) are subject to 15 CFR Part 26, Subpart F, "Government-wide Requirements for Drug-Free Workplace (Grants)" and the related section of the certification form prescribed above applies;

iii. Anti-Lobbying. Persons (as defined at 15 CFR part 28, section 105) are subject to the lobbying provisions of 31 U.S.C. 1352, "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," and the lobbying section of the certification form prescribed above applies to applications/bids for grants, cooperative agreements, and contracts for more than $100,000, and loans and loan guarantees for more than $150,000, or the single family maximum mortgage limit for affected programs, whichever is greater; and

iv. Anti-Lobbying Disclosures. Any applicant that has paid or will pay for lobbying using any funds must submit an SF-LLL, "Disclosure of Lobbying Activities," as required under 15 CFR part 28, appendix B.

8. Lower Tier Certifications

Recipients shall require applicants/bidders for subgrants, contracts, subcontracts, or other lower tier covered transactions at any tier under the award to submit, if applicable, a completed form CD–512, "Certifications Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transactions and Lobbying" and disclosure form, SF-LLL, "Disclosure of Lobbying Activities." Form CD–512 is intended for the use of recipients and should not be transmitted to DOC. SF-LLL submitted by any tier recipient or subrecipient should be submitted to DOC in accordance with the instructions contained in the award document.

9. False Statements

A false statement on an application is grounds for denial or termination of funds and grounds for possible punishment by a fine or imprisonment as provided in 18 U.S.C. 1001.

10. Intergovernmental Review

This action has been determined not to require intergovernmental review.

11. Buy American-Made Equipment or Products

Applicants are hereby notified that they are encouraged, to the extent feasible, to purchase American-made equipment and products with funding provided under this program in accordance with Congressional intent as set forth in the resolution contained in Public Law 103–317, Sections 607 (a) and (b). This provision applies only to Federal appropriations provided under Public Law 103–317.

12. Classification

This action has been determined to be not significant for purposes of E.O. 12866.

This notice contains a collection-of-information requirement subject to the Paperwork Reduction Act. The collection of this information has been approved by OMB, OMB Control Number 0648–0287, with collection approval through 11/30/97. Public reporting burden for this collection of information is estimated to average .5 hours per response for a Registration and 1 hour for an Application for Assistance, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this reporting burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Thomas N. Pyke, Jr. (see **ADDRESSES**), and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (Attention: NOAA Desk Officer). The required forms for registration and application for Federal assistance are appended.

Dated: November 18, 1994.

Thomas N. Pyke, Jr.,

Director, The GLOBE Program.

[Copies of this form may be reproduced so that a completed form can be submitted for each school.]

Registration for a School To Participate in the Globe Program

Name of School _____

Street Address _____

City _____

State _____

ZIP _____

Type of school: elementary _____ intermediate/middle junior high _____ high school _____

Name of Globe Lead Teacher for the School

Name of School Principal _____

Phone numbers to reach the Teacher and Principal (with area code)

Voice ( ) =

FAX ( ) =

Internet address for Teacher, if available

_____

Preferred teacher training period:

February to May 1995 _____

June to August 1995 _____

Certification

I certify that this school meets the "basic requirements" to become a GLOBE school, as described in Part I of this Announcement, and that the school intends to participate in the GLOBE Program for a period of at least 3 years.

Signature of GLOBE Lead Teacher _____

Signature of Principal _____

_____

Identification of Local Educational Agency (e.g. school district) if this school is part of such an Agency

_____

Name, title, and signature of official authorized to sign this certification on behalf of the registered school (e.g. authorized L.E.A. official)

_____

Date

All communications, materials, or other resources under this agreement are administered as a joint project between the registered school and the Federal Government through the authority of the U.S. Department of Commerce, National Oceanic, and Atmospheric Administration under 15 U.S.C. § 1525.

[Copies of this form may be reproduced so that a completed form can be submitted for each school.]

Application for Federal Assistance To Become a Globe School

About Your School

Name of school _____

Street address _____

City _____

State _____

ZIP _____

Type of school: elementary _____ intermediate/middle/junior high _____ high school _____

About Involving Students in GLOBE

How many students are in your school?

_____

How would you plan to involve many of your school's students in GLOBE?

—Would you have the computer and measurement instruments used for GLOBE shared at different times during the school day by two or more classes?

Yes _____ No _____

—Would you create a GLOBE bulletin board in a place where many students could see it?

Yes _____ No _____

—Would you hold one or more school assemblies to share information about the school's participation in GLOBE?

Yes _____ No _____

—Other _____

_____

_____

_____

What percentage of the students in your school would be directly involved in GLOBE, making daily measurements and studying the data and the global environmental images created with worldwide GLOBE student data?

Percent of students _____

About Making GLOBE Measurements

Recognizing the fundamental importance for the GLOBE Program of continuing, long-term, worldwide environmental observations, does your school intend to make GLOBE measurements and transmit the data for GLOBE processing for at least the next 3 years?

Yes _____ No _____

Would your school be able to arrange to have students make GLOBE measurements at times outside the regular school day?

—On weekends? Yes _____ No _____

—During school vacations during the school year? Yes _____ No _____

—Over the summer? Yes _____ No _____

—Would you involve school or community volunteers to help students make these measurements on other than regular school days? Yes _____ No _____

—Other ways of providing coverage on other than regular school days

_____

_____

_____

_____

Do you have funding available to acquire the scientific measurement instruments needed, as identified in this solicitation, which are estimated to cost approximately $150–200 for an elementary school, $300–400 for an intermediate school, and $800–1000 for a high school?

Yes _____ No _____

If No, are you applying for Federal assistance to provide a set of such instruments for use at your school?

Yes _____ No _____

About Working With Other Nearby Schools

Are you planning to collaborate with other nearby schools as you participate in GLOBE?

—With one or more schools that feed your school?

Yes _____ No _____

—With one more schools that your school feeds?

Yes _____ No _____

If Yes, provide the names of the collaborating schools:

_____

Principals of collaborating schools _____

Principals' phone number(s) ( ) -

Have these collaborating schools registered as GLOBE Schools or are they applying for Federal assistance to participate?

Yes _____ No _____

About Involving Your Local Community in GLOBE

How are you planning to involve the local community outside your school in your school's GLOBE activities?

—Invite the public to visit for open houses to see what your students are doing in GLOBE?

Yes _____ No _____

—Invite parents and others to visit after school hours or on weekends to participate hands-on themselves in GLOBE?

Yes _____ No _____

—Prepare articles on your school's GLOBE participation for your school newspaper?

Yes _____ No _____

—Prepare articles on your school's GLOBE participation for local newspapers in your area?

Yes _____ No _____

—Other

_____

_____

_____

_____

About Your School's Involvement in Other Environmental Science or Related Education Programs

Are students in your school already involved in an environmental science or education program that has some of the characteristics of GLOBE?

—Are you making weather or other environmental measurements regularly through the school year?

Yes _____ No _____

—Are you sharing these measurement results with others outside your school?

Yes _____ No _____

—Does your school have an "automated" weather station that records temperature and other measurements all of the time?

Yes _____ No _____

—If Yes, is your weather station part of a community-wide organized effort on the part of a local TV station or other organization?

Yes _____ No _____

—If Yes, please identify the local organization

_____

_____

_____

_____

—Does your school participate in a regional, national, or international environmental education program involving hands-on science?

Yes _____ No _____

If Yes, please identify the program _____

—Does your school participate in a distance education program involving partner schools communicating regularly through the Internet or other means?

Yes _____ No _____

If Yes, please identify the program _____

—Other kinds of involvement?

_____

_____

_____

_____

About Your School's Currently Available Computer and Communications Capabilities to Support GLOBE Participation

Does your school have or are you able to obtain an IBM-compatible or Apple Macintosh computer that meets the minimum GLOBE requirements (see introductory information) and that you would be willing to make available at least 20% of every school day to support GLOBE data entry and related viewing of global visualizations and other related materials?

Yes _____ No_____

If No, are you applying for Federal assistance to provide your school such a computer, including a suitable modem, with the understanding that the school will provide a telephone line for use with this computer that can be used to dial outside telephone numbers, including 800 numbers?

Yes _____ No _____

If Yes, does this computer have a modem that can operate at 9600 bps or faster connected to a telephone line that can be used to dial outside telephone numbers, including 800 numbers?

Yes _____ No _____

If No, are you applying for Federal assistance to provide your school with such a modem, with the understanding that the school will provide a telephone line for use with this computer that can be used to dial outside telephone numbers, including 800 numbers?

Yes _____ No _____

If Yes, is this computer being used by students to access information on the Internet?

Yes _____ No _____

If Yes, are students able to use one of the information access tools that support access to the World Wide Web on the Internet (such as the one called Mosaic)?

Yes_____ No_____

About GLOBE Teacher Training

Are you willing to send a teacher to a workshop to be trained in GLOBE environmental measurements and in the use of associated educational resource materials, for a period of 3 days, at a location in your general part of the country?

Yes_____ No_____

Do you have or can you obtain funding to pay for this teacher's travel expenses to attend such a workshop?

Yes_____ No_____

If No, are you applying for Federal assistance to pay for this teacher's travel expenses to attend such a workshop?

Yes_____ No_____

Are you willing to provide a substitute for this teacher if he or she needs to miss up to 3 school days to receive this training?

Yes_____ No_____

Would you prefer that this teacher be trained in the period February through May 1995, so your school could begin participation in GLOBE this Spring, or would you prefer that this teacher receive training during June through August 1995, so your school could begin participation next Fall?

February through May ____ June through August____

Matching Resources

Does your school propose to commit to obtain some of the needed resources that it needs, but does not yet have, from alternative sources as a form of "matching" the resources requested in this application?

Yes_____ No_____

If Yes, please explain _____

_____

_____

_____

_____

Any Additional Information Your School Would Like To Provide in Support of This Application

Would you like to provide any additional information that would assist in the evaluation of your school's application relative to the GLOBE goals and rating factors?

Yes_____ No_____

If Yes, please do so here: _____

_____

_____

_____

_____

_____

_____

_____

If your school is not selected to receive Federal assistance to enable it to participate in GLOBE, would you like this application made public by the GLOBE Program to support your school's continuing effort to obtain the necessary resources to participate in the program?

Yes_____ No_____

More Information About Your School and Signatures Necessary to Consider Your Application for Federal Assistance

Is your school currently identified as a Chapter 1 school? Yes _____ No _____

Name of GLOBE Lead Teacher for the School

_____

Signature of GLOBE Lead Teacher _____

Name of School Principal _____

Signature of Principal _____

Phone number to reach the Teacher or Principal ( )

_____

Identification of Local Educational Agency (e.g. school district) if this school is part of such an Agency

_____

_____

Name, title, and signature of official authorized to Date sign this application on behalf of this school (e.g. authorized L.E.A. official)

_____

Date

[FR Doc. 94–28947 Filed 22–18–94; 8:45 am]

BILLING CODE 3510–12–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Wool Textile Products Produced or Manufactured in Indonesia

November 17, 1994.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs increasing a limit.

EFFECTIVE DATE: November 18, 1994.

FOR FURTHER INFORMATION CONTACT: Jennifer Tallarico, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of this limit, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–6704. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current limit for the wool subgroup in Group II is being increased for special carryforward.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 58 FR 62645, published on November 29, 1993). Also see 59 FR 55834, published on November 9, 1994.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the MOU dated September 23, 1994, but are designed to assist only in the implementation of certain of its provisions.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

November 17, 1994.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 3, 1994, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Indonesia and exported during the six-month period which began on July 1, 1994 and extends through December 31, 1994.

Effective on November 18, 1994, you are directed to amend the directive dated November 3, 1994 to increase the limit for the subgroup in Group II to 1,542,391 square meters equivalent[1], as provided under the terms of the current bilateral agreement between the Governments of the United States and Indonesia.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 94–28890 Filed 11–22–94; 8:45 am]

BILLING CODE 3510–DR–F

[1] The limit has not been adjusted to account for any imports exported after June 30, 1994.

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to the Procurement List.

SUMMARY: This action adds to the Procurement List service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: December 23, 1994

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740

SUPPLEMENTARY INFORMATION: On September 2, 1994, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (59 F.R. 45667) of proposed addition to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the service, fair market price, and impact of the addition on the current or most recent contractors, the Committee has determined that the service listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the service to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the service.

3. The action will result in authorizing small entities to furnish the service to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the service proposed for addition to the Procurement List.

Accordingly, the following service is hereby added to the Procurement List:

Janitorial/Custodial, U.S. Courthouse Annex, 110 Court Avenue, Des Moines, Iowa

This action does not affect current contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 94–28922 Filed 11–22–94; 8:45 am]

BILLING CODE 6820–33–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

OMB Clearance Request for Environmentally Sound Products

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of new request for OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve a new information collection requirement concerning Environmentally Sound Products.

DATES: Comments may be submitted on or before January 23, 1995.

ADDRESSES: Send comments to Mr. Peter Weiss, FAR Desk Officer, OMB, Room 3235, NEOB, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Beverly Fayson, Office of Federal Acquisition Policy, GSA (202) 501–4755.

SUPPLEMENTARY INFORMATION:

A. Purpose

This information collection requirement in this interim FAR rule (FAR case 92–54) is needed to comply with Section 6002 of the Resource Conservation and Recovery Act (RCRA) (42 U.S.C. 6962). RCRA requires the Environmental Protection Agency (EPA) to designate items which are or can be produced with recovered materials. RCRA further requires agencies to develop affirmative procurement programs to ensure that items composed of recovered materials will be purchased to the maximum extent practicable. Affirmative procurement programs required under RCRA must contain, as a minimum (1) a recovered materials preference program and an agency promotion program for the preference program; (2) a program for requiring estimates of the total percentage of recovered materials used in the performance of a contract, certification of minimum recovered materials content actually used, where appropriate, and reasonable verification procedures for estimates and certifications; and (3) annual review and monitoring of the effectiveness of an agency's affirmative procurement program.

The items for which EPA has designated minimum recovered material content standards are (1) cement and concrete containing fly ash, (2) paper and paper products, (3) lubricating oil containing re-refined oil, (4) retread tires, and (5) building insulation products. The FAR rule also permits agencies to obtain pre-award information from offerors regarding the content of items which the agency has designated as requiring minimum percentages of recovered materials. There are presently no known agency designated items.

In accordance with RCRA, the information collection applies to acquisitions requiring minimum percentages of recovered materials, when the price of the item exceeds $10,000 or when the aggregate amount paid for the item or functionally equivalent items in the preceding fiscal year was $10,000 or more.

Contracting officers will use the information to verify offeror/contractor compliance with solicitation and contract requirements regarding the use of recovered materials. Additionally, agencies will use the information in the annual review and monitoring of the effectiveness of the affirmative procurement programs required by RCRA.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average *30* minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to General Services Administration, FAR Secretariat, 18th & F Streets, NW, Room 4037, Washington, DC 20405, and to the FAR Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

The annual reporting burden is estimated as follows: Respondents,

4,767,908; responses per respondent, *1*; total annual responses, *4,767,908*; preparation hours per response, *.5*; and total response burden hours, *2,383,954*.

Obtaining Copies of Proposals: Requester may obtain copies of OMB applications or justifications from the General Services Administration, FAR Secretariat (VRS), Room 4037, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB clearance request regarding Environmentally Sound Products, FAR case 92–54, in all correspondence.

Dated: November 16, 1994.

Beverly Fayson,

FAR Secretariat.

[FR Doc. 94–28874 Filed 11–22–94; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF ENERGY

Additional Public Scoping Meetings; Preparation of an Environmental Impact Statement (EIS) to Clean Out and Deactivate the Hanford, Washington Plutonium Finishing Plant (PFP) Complex (Except for Storage Areas), to Stabilize PFP Plutonium-Bearing Materials and to Store the Stabilized Material

AGENCY: United States Department of Energy (DOE).

ACTION: Notice of Additional Public Scoping Meetings.

SUMMARY: The Department of Energy (DOE) announced its intent to prepare an EIS pursuant to the National Environmental Policy Act of 1969 (NEPA) in the Thursday, October 27, 1994, **Federal Register** (Volume 59, No. 207, Page 53969). This announcement adds two Public Scoping Meetings to the series of public meetings announced previously.

DATES AND ADDRESSES:

Portland, Oregon, Wednesday, December 7, 1994, 6:30–9:30 pm, Workshop starts at 5:30 pm, Portland Red Lion, Lloyd's Center 1000 Northeast Multnomah, Portland, OR 97232, (503) 281–6111

Seattle, Washington, Thursday, December 8, 1994, 6:30–9:30 pm, Workshop starts at 5:30 pm, Executive Inn, 200 Taylor Avenue, Seattle, WA 98109, (206) 448–9444

SUPPLEMENTARY INFORMATION:

Agenda

Each Public Scoping Meeting will begin with a welcome and brief overview of the proposed EIS and will include workshops beginning one hour earlier on specific items of interest in which the public can ask questions and provide comments to DOE officials. Notes will be taken in the workshops to record public concerns for the workshop record. Each Public Scoping Meeting will be recorded by a public stenographer and will become part of the official record. The Public Scoping Meetings will be chaired by a presiding officer, but will not be conducted as an evidentiary hearing; speakers will not be cross-examined although the presiding officer and DOE representatives may ask clarifying questions. Individuals requesting to speak on behalf of an organization must identify the organization. In the interest of ensuring that all who wish to speak have an opportunity to do so, each individual speaker will be given a 5-minute limit except that a speaker representing an organization (one per organization) will be given a 10-minute limit. Requests to speak at these Public Scoping Meetings may be made by calling the toll-free telephone number, 1–800–516–3740 by 3:00 PM the day before the meeting or by writing to the DOE (see **ADDRESSES** below).

Persons who have not submitted a request to speak in advance may register to do so at the Public Scoping Meeting and will be called on to speak on a first-come, first-served basis as time permits. Speakers are encouraged to provide written versions of their oral comments for the record.

DOE will review scoping comments to determine their applicability to the proposed PFP clean out EIS. An Implementation Plan (IP) for the PFP EIS will provide guidance for preparation of the PFP EIS and establish its scope and content (10 CFR 1021.312). The IP will briefly summarize the scoping comments received and their disposition. The IP will be issued prior to the release of the draft EIS and copies will be made available for inspection.

Submission of Written Comments

Written comments on the scope of the PFP EIS, questions or comments concerning the PFP clean out program, requests for speaking times at the Public Scoping Meetings, and requests for copies of the IP and/or the Draft EIS (DEIS) should be directed to the designated Richland contacts below.

FOR FURTHER INFORMATION CONTACT:

Mr. Jim Mecca, U.S. Department of Energy, P.O. Box 550 (MSIN B1–42), Richland, WA 99352, Attention: NL Peters, Telephone: (509) 946–3683

Mr. Ben Burton, U.S. Department of Energy, P.O. Box 550 (MSIN B1–42), Richland, WA 99352, Telephone: (509) 946–3683

For information on the DOE NEPA process, contact: Carol M. Borgstrom, Director, Office of NEPA Oversight (EH–25), U.S. Department of Energy, 1000 Independence Avenue, S.W., Washington, D.C. 20585, Telephone: 202–586–4600 or leave a message at 1–800–472–2756

EIS technical reports, background data, reference materials, and other related documents will be available either through the contacts listed above or at:

DOE Freedom of Information Reading Room, Forrestal Building, 1000 Independence Ave. S.W., Washington, D.C.

DOE Public Reading Room, Washington State University, Tri-Cities Branch, 100 Sprout Road, Richland, WA 99352

and at the following DOE information repositories:

University of Washington, Suzzallo Library, Government Publication, Seattle, WA 98195

Portland State University, Branford Price Millar Library, SW Harrison and Park, Portland, OR 97207

Gonzaga University, Foley Center, E. 502 Boone, Spokane, WA 99258

Issued in Washington, D.C., on this 15th day of November, 1994.

Elisabeth G. Feldt,

Acting Director, Northwestern Office, Office of Facility Transition and Management, Office of Environmental Management.

[FR Doc. 94–28891 Filed 11–22–94; 8:45 am]

BILLING CODE 6450–01–P

Federal Energy Regulatory Commission

[Docket No. ER92–850–007, et al.]

Louis Dreyfus Electric Power, Inc., et al., Electric Rate and Corporate Regulation Filings

November 15, 1994.

Take notice that the following filings have been made with the Commission:

1. Louis Dreyfus Electric Power, Inc.

[Docket No. ER92–850–007]

Take notice that on October 27, 1994, Louis Dreyfus Electric Power, Inc. (Dreyfus) filed an amendment to its informational filing for the quarter ending June 30, 1994, containing certain information required by the Commission's December 2, 1992 letter order, 61 FERC ¶ 61,303 (1992), in this proceeding. Copies of Dreyfus' informational filing are on file with the Commission and are available for public inspection.

2. Louis Dreyfus Electric Power, Inc.

[Docket No. ER92–850–009]

Take notice that on October 27, 1994, Louis Dreyfus Electric Power, Inc. (Dreyfus) filed its informational filing for the quarter ending September 30, 1994, containing certain information required by the Commission's December 2, 1992 letter order, 61 FERC ¶ 61,303 (1992), in this proceeding. Copies of Dreyfus' informational filing are on file with the Commission and are available for public inspection.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 94–28923 Filed 11–22–94; 8:45 am]

BILLING CODE 6717–01–P

[Docket Nos. TM95–1–32–000, TM94–4–32–000, and TM94–4–32–001]

Colorado Interstate Gas Company; Technical Conference

November 17, 1994.

Take notice that at 10:00 a.m. on Wednesday, November 30, 1994, the Commission staff will convene a technical conference in the above-captioned proceedings. Colorado Interstate Gas Company (CIG) has indicated that, to the extent it will be submitting materials to be treated as confidential under the Commission's regulations, it will work with the parties to maintain confidentiality.

The technical conference will be held at the offices of the Federal Energy Regulatory Commission, 810 First Street, N.E., Washington, D.C.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 94–28928 Filed 11–22–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP95–40–000]

Marathon Oil Company v. Koch Gateway Pipeline Company; Complaint

November 17, 1994.

Take notice that on November 10, 1994, Marathon Oil Company (Marathon), pursuant to Sections 4 and 5 of the Natural Gas Act, 15 U.S.C.A. 717c and 717d (1984), and Rules 206 and 212 of the Commission's Rules of Practice and Procedure, 18 CFR 385.206 and 385.212, submits for filing its complaint against Koch Gateway Pipeline Company (Koch).

Marathon states that since January 1993, Koch has been charging a gathering fee to shippers transporting gas downstream of the Cotton Valley Plant operated by Marathon in Webster Parish, Louisiana. Marathon also asserts that Koch made representations to its shippers that the gas passed through various gathering facilities in order to justify the collection of a gathering fee.

Marathon states that to its knowledge, no facilities being used by Koch to take residue gas from the Cotton Valley Plant ever performed a gathering service. Marathon maintains that the only active interconnect between the Cotton Valley Plant and Koch facilities is at SLN 4283, which refers to metering facilities that are downstream of the Cotton Valley Plant and only perform a transportation-related service.

Marathon requests the Commission to find that (i) Koch does not perform a gathering service downstream of the Cotton Valley Plant; (ii) Koch violated its tariff and NGA § 4 by charging a gathering rate to shippers for non-existent gathering services; and (iii) the metering facilities at SLN 4283 downstream of the Cotton Valley Plant perform a transmission function.

Based on these findings, Marathon requests that the Commission order Koch to refund, with interest, all gathering charges collected by Koch on gas volumes received at the tailgate of the Cotton Valley Plant, and to grant such further relief as the Commission may find appropriate under the circumstances.

Any person desiring to be heard or to protest said complaint should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.214, 385.211. All such motions or protests should be filed on or before December 19, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. Answers to this complaint shall be due on or before December 19, 1994.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 94–28926 Filed 11–22–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP95–43–000]

Northwest Alaskan Pipeline Company; Tariff Changes

November 17, 1994.

Take notice that on November 15, 1994, Northwest Alaskan Pipeline Company (Northwest Alaskan), tendered for filing in Docket No. RP95–43–000, to become part of its FERC Gas Tariff, Original Volume No. 2, Thirty-Fifth Revised Sheet No. 5, to become effective January 1, 1995.

Northwest Alaskan states that it is submitting Thirty-Fifth Revised Sheet No. 5 reflecting an increase in total demand charges for Canadian gas purchased by Northwest Alaskan from Pan-Alberta Gas Ltd. (Pan-Alberta) and resold to Northwest Alaskan's two U.S. purchasers: Pan-Alberta Gas (U.S.) Inc. (Pan-Alberta (U.S.)) under Rate Schedules X–1, X–2, and X–3, and Pacific Interstate Transmission Company (PIT) under Rate Schedule X–4.

Northwest Alaskan states that it is submitting Thirty-Fifth Revised Sheet No. 5 pursuant to the provisions of the amended purchase agreements between Northwest Alaskan and, Pan-Alberta (U.S.), and PIT, and pursuant to Rate Schedules X–1, X–2, X–3, and X–4, which provide for Northwest Alaskan to file 45 days prior to the commencement of the next demand charge period (January 1, 1995 through June 30, 1995) the demand charges and demand charge adjustments which Northwest Alaskan will charge during the period.

Northwest Alaskan states that a copy of this filing has been served on Northwest Alaskan's customers.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests should be filed on or before November 25, 1994. Protests

will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 94–28927 Filed 11–22–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP94–301–000]

Stingray Pipeline Company; Informal Settlement Conference

November 17, 1994.

Take notice that an informal settlement conference will be convened in this proceeding on December 6, 1994, at 10:00 a.m., at the offices of the Federal Energy Regulatory Commission, 810 First Street, N.E., Washington, D.C., for the purpose of exploring the possible settlement of issues in this proceeding.

Any party, as defined by 18 CFR 385.102(c) (1994), or an participant, as defined by 18 CFR 385.102(b) (1994), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations at 18 CFR 214 (1994).

For additional information, please contact Warren C. Wood at (202) 208–2091 or Marc G. Denkinger at (202) 208–2215.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 94–28925 Filed 11–22–94; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5108–9]

Access to Confidential Business Information by TRC Environmental Corporation and Its Team Subcontractors

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA awarded Region II Enforcement Support Services (ESS) Contract 68–W4–0020 to prime contractor, TRC Environmental Corporation (TRC). EPA has authorized TRC, including its team subcontractors, American Management Systems, DynCorp, Viar, Industrial Economics Corporation, Joseph Spina Associates, Ecology and Environment, and InfoPro, access to information in Region II Superfund files which has been submitted to EPA under the environmental statutes administered by the Agency. Some of this information may be claimed or determined to be confidential business information (CBI).

DATES: Comments concerning CBI access will be accepted on December 28, 1994.

FOR FURTHER INFORMATION CONTACT: John Bachmann, Contracting Officer, U.S. Environmental Protection Agency (FAMB), Jacob K. Javits Federal Building, 26 Federal Plaza, New York, NY 10278. Telephone (212) 264–2702.

SUPPLEMENTARY INFORMATION: Under contract no. 68–W4–0020, TRC provides agency-wide information management support services to the Environmental Protection Agency for the operation of dockets, records management support programs, records centers, and file rooms in certain Headquarters, Regional, Laboratory, and other offices. In performing these tasks, TRC employees have access to Agency documents for purposes of document processing, filing, abstracting, analyzing, inventorying, retrieving, tracking, etc. The documents to which TRC has access potentially include all documents submitted under the Resource Conservation and Recovery Act, Clean Air Act, Clean Water Act, and Comprehensive Environmental Response, Compensation, and Liability Act. Some of these documents may contain information claimed as CBI.

Pursuant to EPA regulations at 40 CFR Part 2, Subpart B, EPA has determined that TRC requires access to CBI to perform the work required under the contract. These regulations provide for five days notice before contractors are given CBI.

TRC is required by contract to protect confidential information. When TRC's need for the documents is completed, TRC will return them to EPA.

Dated: October 16, 1994.

Jeanette Brown,

Acting Director of Office of Acquisition Management.

[FR Doc. 94–28839 Filed 11–22–94; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License; Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR part 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

Jaro International, L.L.C., 1022 Woodmill Drive, Cranbury, NJ 08512, Officer: Janet H. Chen, General Manager

New World Freight Systems, Inc., 1067 Sneath Lane, San Bruno, CA 94066, Officers: Jung Ho Lee, President, Yon Hui Lee, Vice President, Lesa, Hyon, Secretary

World Cargo Corporation, 4408 NW 74th Ave., Miami, FL 33166, Officer: Diana Obregon-Bader, President

Ameera Yassir dba Mona Forwarding Co., 6430 Richmond Ave., #340, Houston, TX 77057, Sole Proprietor

Sterling Cargo International, Inc., 3010 N. Airfield Dr., Bldg. 1, Ste. 2, DEW Airport, TX 75261, Officers: Charles R. Green, President, Patricia P. Chilton, Vice President

Worldwide Express, Inc., 2000 North Loop, Ste. 203, Lester, PA 19113, Officer: Joyce A. Thompson, President

America's World Freight, Inc., 7370 N.W. 35th Street, Miami, FL 33122, Officers: Rene Aljure, President, Ingrid Dinse Aljure, Vice President

Ocean-5 Express Line, Inc., 520E Carson Plaza Court, Ste. #205, Carson, CA 90746, Officers: Susan Chang, President, Bruce Yun, Director

Dated: November 17, 1994.

By the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 94–28852 Filed 11–22–94; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Consumers Bancorp, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the

application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than December 16, 1994.

A. Federal Reserve Bank of Cleveland (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. Consumers Bancorp, Inc., Minerva, Ohio; to become a bank holding company by acquiring 100 percent of the voting shares of Consumers National Bank, Minerva, Ohio (in organization).

B. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. Totalbank Corporation of Florida, Miami, Florida; to acquire 100 percent of the voting shares of Florida International Bank, Perrine, Florida.

2. Pea River Capital Corporation, Elba, Alabama; to become a bank holding company by acquiring 100 percent of The Peoples Bank of Coffee County, Elba, Alabama (in organization).

C. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Marshall & Isley Corporation, Milwaukee, Wisconsin; to acquire 24.90 percent of the voting shares of Financial Services Corporation of the Midwest, Rock Island, Illinois, and thereby indirectly acquire Rock Island Bank, Rock Island, Illinois.

D. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Battle Creek State Company, Battle Creek, Nebraska; to become a bank holding company by acquiring 100 percent of the voting shares of Battle Creek State Bank, Battle Creek, Nebraska.

2. First State Bancshares, Inc., Scottsbluff, Nebraska to acquire 100 percent of the voting shares of Liberty Industrial Bank, Colorado Springs, Nebraska.

3. Mountain Bancshares, Inc., Los Alamos, New Mexico; to become a bank holding company by acquiring 100 percent of the voting shares of Mountain Community Bank, Los Alamos, New Mexico.

E. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Menard Bancshares, Inc., Menard, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of Menard National Bank, Menard, Texas.

Board of Governors of the Federal Reserve System, November 16, 1994.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 94-28897 Filed 11-22-94; 8:45 am]

BILLING CODE 6210-01-F

First Virginia Banks, Inc. ; Notice of Application to Engage de novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 8, 1994.

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. First Virginia Bbanks, Inc., Falls Church, Virginia; to engage *de novo* through its subsidiary First General Leasing Company, Falls Church, Virginia, in providing leasing services to the public generally, pursuant to § 225.25(b)(5) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, November 16, 1994.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 94-28899 Filed 11-22-94; 8:45 am]

BILLING CODE 6210-01-F

Firstar Corporation, et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a

hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than December 8, 1994.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Firstar Corporation, Milwaukee, Wisconsin; through its subsidiary Firstar Corporation of Illinois, Milwaukee, Wisconsin, to acquire First Colonial Investment Services, Inc. Rosemont, Illinois, and thereby engage in providing discount securities brokerage services, pursuant to § 225.25(b)(15) of the Board's Regulation Y.

B. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. BankAmerica Corporation, San Francisco, California; to acquire through its subsidiary Bank of America, FSB, Portland, Oregon; Arbor National Holdings, Inc., Uniondale, New York, and thereby engage in originating, purchasing, and servicing residential first mortgage loans, pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, November 16, 1994.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 94–28898 Filed 11–22–94; 8:45 am]

BILLING CODE 6210–01–F

William Mansfield Jennings, Jr., et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 8, 1994.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. William Mansfield Jennings, Jr.; to acquire 41.49 percent of the voting shares of MGeorgia Bankshares, Inc., Hawkinsville, Georgia, and thereby indirectly acquire Pulaski Banking Company, Hawkinsville, Georgia.

B. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Hoeme Family Partnership, Scott City, Kansas; to acquire 28.34 percent of the voting shares of First National Bancshares of Scott City, Ltd. Scott City, Kansas, and thereby indirectly acquire First National Bank of Scott City, Scott City, Kansas.

Board of Governors of the Federal Reserve System, November 16, 1994.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 94–28900 Filed 11–22–94; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0012]

Methods of the Allergenic Products Testing Laboratory; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Methods of the Allergenic Products Testing Laboratory" (the methods document), dated October 1993. The methods document provides the technical details for performing in vivo and in vitro analytical methods acceptable to FDA to ensure the identity and relative potency of allergenic extracts. The methods document is intended for use by manufacturers of licensed allergenic extracts, sponsors of investigational new drug applications for allergenic extracts, and other interested parties.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the methods document to the Congressional and Consumer Affairs Branch (HFM–12), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, or call FDA's automated information system at 301–594–1800. Send two self-addressed adhesive labels to assist that office in processing your requests. Persons with access to INTERNET may request the methods document from CBER–INFO@A1.CBER.FDA.GOV. Submit written comments on the methods document to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the methods document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of the methods document that was prepared by the Laboratory of Immunobiochemistry (HFM–422), Division of Allergenic Products and Parasitology, Office of Vaccine Research and Review, Center for Biologics Evaluation and Research, FDA. This methods document is a revision of "Methods of the Laboratory of Allergenic Products," dated March 1987, which previously was available to the public under 21 CFR part 20 and § 10.90(b)(10) (21 CFR 10.90(b)(10)).

The methods document sets forth the in vitro and in vivo methods used in the Laboratory of Immunobiochemistry for determining the identity and relative potency of investigational and approved allergenic extracts. The in vitro methods include the following qualitative and quantitative methods: Agarose diffusion, isoelectric focusing (IEF), radial immunodiffusion (RID), enzyme-linked immunosorbent assay (ELISA), radioallergosorbent test (RAST), ninhydrin, blotted isoelectric focusing-light (BIEF–LIGHT), and blotted radio-immuno isoelectric focusing (BRIEF). The in vivo methods include quantitative intradermal tests.

The methods document is not intended to constitute a comprehensive reference of analytical methods appropriate for allergenic extract testing, and all methods described are not necessarily applicable to all allergenic extracts. Rather, the methods document provides representative analytical

methods that would be acceptable to FDA for allergenic extract testing. The use of alternative analytical methods may be considered but should be discussed with FDA prior to use to prevent the possible expenditure of resources on methods that FDA may later determine to be unacceptable. This notice of availability is announced under § 10.90(b)(10), which provides that particular analytical methods may be included in the public file for a particular purpose.

FDA is requesting comments from interested parties concerning the methods document. These comments will be considered in determining whether further revision of the methods document is warranted.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the methods document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94–28858 Filed 11–22–94; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94F–0393]

Asahi Denka Kogyo K. K., Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Foods and Drug Administration (FDA) is announcing that Asahi Denka Kogyo K. K. has filed a petition proposing that the food additive regulations be amended to provide the expanded safe use of phosphorous acid, cyclic neopentanetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl)ester as an antioxidant and/or stabilizer at a level not to exceed 0.25 percent by weight in olefin copolymers in contact with certain food categories, and at levels not to exceed 0.10 percent by weight in either olefin copolymers or polypropylene in contact with certain other food categories.

DATES: Written comments on the petitioner's environmental assessment by December 23, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5)(21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 4B4434) has been filed by Asahi Denka Kogyo K. K., 2, Shirahata 5-Chome, Urawa City, Saitama 366, Japan. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers in polymers* (21 CFR 178.2010) to provide for the expanded safe use of phosphorous acid, cyclic neopentanetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl)ester for use (i) at levels not to exceed 0.25 percent by weight of olefin polymers complying with § 177.1520 (21 CFR 177.1520) in contact with foods of types I, II, III, IV–B, VI–B, and VIII, as described in Table 1, and under conditions of use B through H described in Table 2 of § 176.170(c) (21 CFR 176.170(c)) of this chapter, and with foods of types IV–A, V, VI–A, VI–C, VII–A, and IX, under conditions of use C through G, as described in § 176.170(c), Tables 1 and 2, respectively; and (ii) at levels not to exceed 0.10 percent by weight of either olefin polymers or polypropylene complying with § 177.1520 which may be used only in contact with foods of types IV–A, V, VI–C, VII–A, and IX, under conditions of use H, as described in § 176.170(c) of this chapter, Tables 1 and 2 respectively.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before December 23, 1994, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: November 14, 1994.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 94–28859 Filed 11–22–94; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94F–0381]

The Dow Chemical Co., Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Dow Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of glyceryl polyoxypropylene triol;α,α′,α″-1,2,3-propanetriyltris[ω-hydroxypoly(oxypropylene)], average molecular weight 250, as a reactant in the preparation of polyester and polyurethane resins used as components of adhesives for food-contact articles.

DATES: Written comments on petitioner's environmental assessment by December 23, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 4B4435) has been filed by the Dow Chemical Co., 1803 Bldg., Midland, MI 48674–1803. The petition proposes to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) to provide for the safe use of glyceryl polyoxypropylene triol;

α,α′,α″-1,2,3-propanetriyltris[ω-hydroxypoly(oxypropylene)], average molecular weight 250, as a reactant in the preparation of polyester and polyurethane resins used as components of adhesives for food-contact articles.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before December 23, 1994, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: November 14, 1994.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 94–28861 Filed 11–22–94; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94F–0398]

Eastman Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Eastman Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 1,4-cyclohexanedicarboxylic acid as a polybasic acid for use in polyester resins intended for food-contact coatings.

DATES: Written comments on the petitioner's environmental assessment by December 23, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3092.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 4B4431) has been filed by Eastman Chemical Co., P.O. Box 1994, Kingsport TN, 37662. The petition proposes to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) to provide for the safe use of 1,4-cyclohexanedicarboxylic acid as a polybasic acid for use in polyester resins intended for food-contact coatings.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4 (b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before December 23, 1994, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: November 14, 1994.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 94–28862 Filed 11–22–94; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94F–0395]

Ecological Chemical Products Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ecological Chemical Products Co., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2-hydroxy-propanoic acid homopolymer and (2-hydroxy-propanoic acid/caprolactone) block copolymer as components of adhesives.

DATES: Written comments on the petitioner's environmental assessment by December 23, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3092.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 4B4432) has been filed by Ecological Chemical Products Co., 305 Water St., Newport, DE 19804. The petition proposes to amend § 175.105 *Adhesives* (21 CFR 175.105) of the food additive regulations to provide for the safe use of 2-hydroxy-propanoic acid homopolymer and (2-hydroxy-propanoic acid/caprolactone) block copolymer.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4 (b)), the agency is placing the environmental assessment submitted with the petition that is the subject of the notice on public display at the Dockets

Management Branch (address above) for public review and comment. Interested persons may, on or before December 23, 1994, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: November 14, 1994.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety Applied Nutrition.

[FR Doc. 94–28860 Filed 11–22–94; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[OPL–003–N]

Medicare Program; Meeting of the Practicing Physicians Advisory Council

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for December 12, 1994, from 8 a.m. until 5 p.m. e.s.t.

ADDRESSES: The meeting will be held in Room 800, 8th Floor of the Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Martha DiSario, Executive Director, Practicing Physicians Advisory Council, Room 425–H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, (202) 690–7874.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act, as added by section 4112 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Public Law 101–508, enacted on November 5, 1990), to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms.

The current members are: Gary C. Dennis, M.D.; Catalina E. Garcia, M.D.; Harvey P. Hanlen, O.D.; Kenneth D. Hansen, M.D.; Isabel V. Hoverman, M.D.; Sandral Hullett, M.D.; Jerilynn S. Kaibel, D.C.; William D. Kirsch, D.E., M.P.H.; Marie G. Kuffner, M.D.; Katherine L. Markette, M.D.; Kenton K. Moss, M.D.; Isadore Rosenfeld, M.D.; Richard B. Tompkins, M.D.; Kenneth M. Viste, Jr., M.D.; and James C. Waites, M.D. The chairperson is Richard B. Tompkins, M.D.

The eleventh meeting of the Council will be held on December 12, 1994. The following topics will be discussed at that meeting:

- Autopsy recognition.
- Proposed billing and payment policy for automated multi-channel laboratory testing.
- Increasing physicians' participation in the Health Care Quality Improvement Program (HCQIP). HCQIP is a program to support providers' and physicians' operational and quality improvement efforts. The efforts produce measurable improvements in process and outcome while building the capacity for improvement. These activities, as carried out by local peer review organizations, are called projects. We are also working with outside organizations to increase physician participation in the development and improvement of these projects. We have also convened a steering committee of leaders in the physician community to help us develop quality indicators for use in these projects.
- Medicare and Medicaid common data initiative. The topic concerns essential encounter data that can be used for utilization analysis, appropriate rate-setting, but most importantly, as a data template to examine clinical outcome measures.

Individuals or organizations who wish to make 5-minute oral presentations on the above issues must contact the Executive Director to be scheduled. For the name, address, and telephone number of the Executive Director, see the **FOR FURTHER INFORMATION CONTACT** section at the beginning of this notice. The number of oral presentations may be limited by the time available.

Anyone who is not scheduled to speak may submit written comments to the Executive Director. The meeting is open to the public, but attendance is limited to the space available on a first-come basis.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Public Law 92–463 (5 U.S.C. App. 2, section 10(a)); 45 CFR Part 11.)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: November 14, 1994.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 94–28853 Filed 11–22–94; 8:45 am]

BILLING CODE 4120–01–P

Health Resources and Services Administration

Advisory Council; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of December 1994:

Name: Council on Graduate Medical Education Medical Licensure Subgroup.

Time: December 13, 1994, 10:00 a.m.

Place: Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, VA 22202. Open for entire meeting.

Purpose: Review the operations of the American Medical Association's National

Credentials Verification System and recommend if appropriate, an alternative credentials verification system or process for physicians that assures nondiscriminatory policies and practices in the operation of the system.

Review the policies and practices of State Medical Boards in licensing international medical graduates and U.S. medical graduates, and determine the effects of such policies and practices.

Report and make recommendations to Congress, the Secretary of Health and Human Services and the Council on Graduate Medical Education regarding the finding of the subgroup.

Agenda: The agenda for the second meeting of the Council on Graduate Medical Education Medical Licensure Subgroup includes a review of the results of the pilot test of the proposed questionnaire for the survey of selected State medical boards. Presentation will be made by the Educational Commission for Foreign Medical Graduates (ECFMG) and the Federation of State Medical Boards (FSMB) regarding their operations and their views on the development of a private sector national credentials verification system.

Anyone requiring information regarding the meeting should contact Stanford Bastacky, D.M.D., M.H.S.A. telephone (301) 443–6785; Division of Medicine, Bureau of Health Professions, Health Resources and Services Administration, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Agenda Items are subject to change as priorities dictate.

Dated: November 17, 1994.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 94–28896 Filed 11–22–94; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

AGENCIES: U.S. Public Health Service, Department of Health and Human Services, Agricultural Research Service and Office of Food, Nutrition, and Consumer Services, U.S. Department of Agriculture.

ACTION: Dietary Guidelines Advisory Committee: Notice of Meeting; Extension of Written Comment Period; Opportunity to Provide Oral Comment.

SUMMARY: The Department of Health and Human Services (HHS) and the Department of Agriculture (USDA)(a) provide notice of the second meeting of the Committee, (b) extend the written comment period, and (c) solicit public testimony.

DATES: (1) The Committee will meet January 11, 1995, for a full-day meeting beginning at 9:00 a.m. p.s.t., January 12, 1995, for a half-day meeting beginning at 9:00 a.m. p.s.t., and January 13, 1995 for a full-day meeting beginning at 9:00 a.m. p.s.t. at the Holiday Inn Financial District/Chinatown, Jade Room, 750 Kearny Street, San Francisco, California 94108. (2) Oral testimony, from preregistered participants, will be accepted January 11, 1995, for one half day beginning 9:00 a.m. (3) Written comment on the Guidelines should be submitted by January 31, 1995, to insure consideration by the Committee.

FOR FURTHER INFORMATION CONTACT: Karil Bialostosky, M.S., Executive Secretary from HHS to the Dietary Guidelines Advisory Committee, Office of the Assistant Secretary for Health, Department of Health and Human Services, Room 2132, Switzer Building, 330 C Street, SW., Washington, DC 20201, (202) 205–9007.

SUPPLEMENTARY INFORMATION:

Dietary Guidelines Advisory Committee Task

The eleven-member Committee appointed by the Secretaries of the two Departments reflects the commitment by the Department of Health and Human Services and Agriculture to the provision of sound and current dietary guidance to consumers. The National Nutrition Monitoring and Related Research Act of 1990 (Pub. L. 101–445) requires the Secretaries of HHS and USDA to publish the *Dietary Guidelines for Americans* at least every five years.The Directory Guidelines Advisory Committee will recommend revisions to the Secretaries for the 1995 edition of *Nutrition and Your Health: Dietary Guidelines for Americans.*

Announcement of Meeting

The Committee's second meeting will be January 11, 1995, beginning at 9:00 a.m. (full-day meeting), January 12, 1995, beginning at 9:00 a.m. (half-day meeting), and January 13, 1995, beginning at 9:00 a.m. (full-day meeting), p.s.t. The meeting will be held at the Holiday Inn Financial District/ Chinatown, Jade Room, 750 Kearny Street, San Francisco, California 94108. The agenda will include (a) oral testimony from preregistered people or groups (b) discussion of drafts prepared by members taking into account public testimony and written comments submitted to date, and (c) formulation of plans for future work of the Committee.

Public Participation at Meeting

The meeting is open to the public. However, space is limited for all sessions. Oral testimony from the public will be accepted for one half day, beginning at 9:00 a.m., on January 11, 1994. Requests to testify should be mailed by January 1, 1995, to Karil Bialostosky, Office of the Assistant Secretary for Health, Department of Health and Human Services, 330 C Street S.W., Room 2132, Switzer Building, Washington, D.C. 20201, or faxed to (202) 205–9478. Presenters are requested to disclose their affiliation and their source of funding to attend the meeting and limit their comments to five minutes. The Committee requests the submission of written copies of verbal statements. Please call Karil Bialostosky (202/205–9007) by December 30, if you will require a sign language interpreter at the meeting.

Written Comment

By this notice, the Committee is extending the deadline to submit written comments, views, information, and data pertinent to review of the *Dietary Guidelines for Americans.* Comments should be sent to Karil Bialostosky, at the Office of the Assistant Secretary for Health, Department of Health and Human Services, Switzer Building, Room 2132, 330 C Street, S.W., Washington, D.C. 20201, by January 31, 1995, to insure consideration by the Committee.

Dated: November 10, 1994.

J. Michael McGinnis,

Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion), U.S. Department of Health and Human Services.

[FR Doc. 94–28914 Filed 11–22–94; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–068–01–7123–00–6592]

Emergency Closure of Public Lands; California

AGENCY: Bureau of Land Management Department of the Interior.

ACTION: Emergency closure of public lands to motorized vehicles includes the area encompassed by: vehicle use southeast of Barstow along and including the road south of the Nebo Marine base, east to Camprock road, south to Northside (Lucerne Valley),

west to state route 247, north to the powerline road, San Bernardino County, California.

SUMMARY: In accordance of title 43, Code of Federal Regulations 8341.2, notice is hereby given that all lands below, listed lands and roads located therein administrated by the Bureau of Land Management (BLM) have been closed to all motorized vehicle use; except for BLM operation and maintenance vehicles, law enforcement vehicles and other vehicles specifically authorized by an authorized officer of the Bureau of Land Management; and except for the list of routes administered by the BLM which are identified below, which will be signed open.

This closure affects ALL of the public lands, from the powerline southeast of Barstow (south of the Nebo Marine Base), east to Camprock road, south to Northside road (Lucerne Valley), bordered by State route 247 to the west:

OPEN ROUTES: Open routes of travel have been established through the closed area. These routes are signed as "open routes" on-site while all other routes are closed. A map of the closure and the specific open routes are available from the Bureau of Land Management, 150 Coolwater Lane, Barstow CA 92311, (619)-256–3591.

DATES: The emergency closure goes into effect and will remain in effect for or until a formal motor vehicle route planning and designation has been completed for this area in accordance with title 43, Code of Federal Regulations 8342.2, whichever comes first; or until the Authorized officer determines it is no longer needed. This closure may be extended at the authorizing officer's discretion if formal route designation has not yet occurred.

SUPPLEMENTARY INFORMATION: This closure is required to mitigate the impacts of unregulated street-legal and non-street legal motorized use in a class "L" limited use area as designated in the California Desert District Conservation Area Plan (1980), as amended. This area is important to wildlife, upland game birds, desert tortoise habitat, and the desert tortoise, a threatened species (listed in 1989 as endangered, downgraded to threatened in 1990). This area is impacted by the neighboring Stoddard Valley OHV Area and Johnson Valley OHV Area. Route proliferation is occurring within the area impacting the habitat of the desert tortoise. This closure will allow for permitted use, including but not limited to grazing, recreation and mining.

PENALTIES: Failure to comply with this closure is punishable by a fine not to exceed $100,000 and/or imprisonment not to exceed 12 months.

FOR FURTHER INFORMATION CONTACT: Area Manager Barstow Resource Area (619 256–2729). Maps of the closure will be posted at the closest Daggett, Barstow and Lucerne Valley Post Offices and may also be obtained from the Barstow Resource Area, 150 Coolwater Lane, Barstow CA 92311.

Dated: November 8, 1994.

Tim Read,

Acting Area Manager, Barstow Resource Area.

[FR Doc. 94–28880 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–40–P

[CA–068–01–7123–00–6592]

Temporary Closure of Public Lands in San Bernardino County, CA

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Notice of Temporary Closure of Public Lands in San Bernardino County, CA.

SUMMARY: In accordance with Title 43, Code of Federal Regulations 8364.1, notice is hereby given that certain Public Lands located north and east of Lucerne Valley, California are closed to entry with additional lands being closed to motorized vehicle use from November 24, 1994 through November 27, 1994. This closure begins at the intersection of Anderson Dry Lake Road and Camp Rock Road and continues NW approximately 23 miles to Highway 247. This 23 mile section includes the 1994 American Motorcycle Association's Point-to-Point Event's connecting route between Johnson Valley and Stoddard Valley. The Public Lands which are closed to entry encompass the 23 mile event route plus one mile on either side of the route. The additional lands that are closed to motorized vehicle use include all designated routes that cross the 23 mile event route.

Order: Effective at 0600 hours (6:00 a.m.p.s.t), Thursday November 24, 1994 through 1700 hours (5:00 p.m.p.s.t) Sunday, November 27, 1994, all public lands crossed by the 1994 American Motorcycle Association's Point-to-Point Event's connecting route between Johnson Valley and Stoddard Valley and all public lands that are within one mile on either side of this route will be closed to entry. The legal land descriptions for the public lands affected by this closure to entry are as follows:

San Bernardino Baseline and Meridian

T.8N.,R.1W.,
Secs. 34, 35
T.7N.,R.1W.,
Secs. 2, 3, 4, 9, 10, 11, 12
T.7N, R.1E.,
Secs.
6, 7, 8, 15, 18, 19, 20, 21, 22, 26, 27, 28, 30, 31, 32, 34
T.6N, R.1E.,
Secs. 2, 3, 10, 11, 12, 14, 15
T.6N, R.2E.,
Secs. 6, 7, 8, 18, 19, 20, 27, 28, 30, 32

No person may enter any portion of this closure.

Also effective at 0600 hours (6:00 a.m.p.s.t), Thursday November 24, 1994 through 1700 hours (5:00 p.m.p.s.t) Sunday, November 27, 1994, all designated routes on public lands which intersect the 1994 American Motorcycle Association's Point-to-Point Event's connecting route between Johnson Valley and Stoddard Valley will be closed to motorized vehicle use. The descriptions for these additional closed routes are as follows:

San Bernardino Baseline and Meridian

1. The connecting route that starts from the pipeline road (SV 183) and leads approximately two and one half miles northwest to the event route. The road begins in the northeast quarter of T.7N, R.1W, sec. 23 crosses sections 14 and 11 and ends in the southwest quarter of T.7N, R.1W, sec. 2.

2. An approximate six and one half mile portion of the pipeline road (SV183) that begins in the northwest quarter of T.7N, R.1W, sec. 24, crosses T.7N, R.1E secs. 19, 20, 17, 16, 15, 14, 13 and ends at a road junction in the southwest quarter of T.7N, R.1E, sec. 15.

3. An approximate eight mile portion of the pipeline route that runs north from Harrod Road to SV183. The closure begins near the center of T.6N, R.1E, sec. 23, crosses T.6N, R.1E, secs. 23, 14, 11, 2, 1 and T.7N, R.1E, secs. 36, 25, 24, 23, branches off the pipeline in the northeast quarter of sec. 23, runs northwest across sec. 14 and ends at SV 183 in the southeast quarter of T. 7N, R. 1E, sec. 11.

4. An approximate five mile section of route that begins on the west section line of T. 6N, R. 1E, sec. 33 and runs northeast through secs. 33, 28, 22, 15, 14, 11 and ends at the event route in the north half of T.6N, R.1E, sec. 11.

5. An approximate one mile section of the pipeline route that begins at a road junction in the northeast quarter of T.6N, R. 1E, sec. 23, runs northeast through T.6N, R.1E, secs. 23, 14, 13 and ends at a natural roadblock in the northeast quarter of T. 6N, R.1E, sec. 13.

6. An approximate seven mile section of the pipeline route that begins at Camp Rock Road in the southwest quarter of T 6N., R.2E., sec. 14 and runs

southwest through T.6N, R.2E., sec 14, 13, 22, 21, 28, 29, 30, 31, T. 6N, R.1E., sec. 36, 35 and ends at a pipeline junction in the southwest quarter of T. 6N., R.1E., sec. 35.

A map showing the areas and routes affected by the closure is available from the Barstow Resource Area Office, 150 Coolwater Lane, Barstow, CA 92311.

No person may use, drive, move, transport, let stand, park, or have charge or control over any type of motorized vehicle within this closure area or on closed routes.

Exemptions to this order are granted to the following: The five hundred event participants and event officials authorized by the Bureau of Land Management's authorized officer.

Employees of valid right-of-way holders in the course of duties associated with the right-of-way.

Holders of valid lease(s) and/or permit(s) and their employees in the course of duties associated with the lease and/or permit.

All persons expressly authorized by the Barstow Area Manager.

All other exemptions to this order are by written authorization of the Barstow Resource Area Manager. Person(s) seeking an exemption may submit their requests in writing to the Barstow Resource Area Manager (150 Coolwater Lane, Barstow, CA 92311). The requests must include a detailed description outlining the purpose or need for the exemption, specific areas to be used, and the dates of the exemption.

BACKGROUND: The purpose of this temporary closure is to protect all Public Land resources on or adjacent to the 1994 American Motorcycle Association's Point-to-Point Event's connecting route between Johnson Valley and Stoddard Valley and associated areas from large scale foot and horse traffic and unmanaged vehicle use. Resources most critical to the areas affected by this closure are the desert tortoise and its habitat. The desert tortoise is listed as a threatened species under the Federal Endangered Species Act and is afforded increased protection under the terms of the Act.

EFFECTIVE DATE: This closure will be in effect from 0600 hours (6:00 a.m.p.s.t), Thursday November 24, 1994 through 1700 hours (5:00 p.m.p.s.t) Sunday, November 27, 1994.

FOR FURTHER INFORMATION CONTACT: Area Manager, Barstow Resource Area, 150 Coolwater Lane, Barstow, CA 92311, (619) 256–3591.

SUPPLEMENTARY INFORMATION: The environmental assessment and maps showing the areas and routes affected by this closure order are available by contacting the aforementioned office.

Authority for this temporary closure order is found in 43 CFR 8364.1. Violation of this closure is punishable by a fine not to exceed $100,000 and/or imprisonment not to exceed 12 months.

Dated: November 8, 1994.

Tim Read,

Acting Area Manager, Barstow Resource Area.

[FR Doc. 94–28881 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–40–P

[OR–080–05–6350–00 GP–5–025]

Resource Management Plan; Salem District, Salem, OR

ACTION: Notice of Availability of the Proposed Resource Management Plan/Final Environmental Impact Statement for the Salem District, Salem, Oregon.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1970, section 202(f) of the Federal Land Policy and Management Act of 1976, and 43 CFR part 1610, a proposed resource management plan/final environmental impact statement (PRMP/FEIS) for the Salem District, Oregon, has been prepared and is available for review and comment. The PRMP/FEIS describes and analyzes future options for managing approximately 398,100 acres of mostly forested public land and 27,800 acres of non-Federal surface ownership with federal mineral estate administered by the Bureau of Land Management in 12 counties in northwest Oregon.

PUBLIC PARTICIPATION: Copies of the PRMP/FEIS and a summary of it may be obtained from the Salem District Office. Public reading copies will be available for review at local public libraries, government document depository libraries, and at the following BLM locations:

Office of External Affairs, Main Interior Building, Room 5647, 1849 C Street, N.W., Washington, D.C. 20240

Public Room, Oregon State Office, 1515 S.W. Fifth, Portland, OR 97201

Salem District Office, 1717 Fabry Road S.E., Salem, OR 97306

Tillamook Resource Area Office, 4610 Third St., Tillamook, OR 97141

All other BLM offices in western Oregon.

An open house with the opportunity to discuss the PRMP/FEIS will be held at the Salem District Office. The open house will be held on December 1, 1994, from 1–5 p.m. and 7–9 p.m.

There will be a 30-day comment/protest period beginning November 18, 1994, when the Environmental Protection Agency is expected to publish its Notice of Availability in the **Federal Register**. Anyone can comment on the PRMP/FEIS, but only those persons or organizations who participated in the planning process leading to this PRMP/FEIS may protest. The comment/protest period will close December 19, 1994.

A protesting party may raise only those issues which were submitted for the record during the planning process. Protests of proposed plan elements that merely adopt decisions made in the 1994 Record of Decision for Amendments to Forest Service and Bureau of Land Management Planning Documents Within the Range of the Northern Spotted Owl (SEIS ROD) will be dismissed, as the director has no authority to overrule those decisions. Details of the protest process can be found in the PRMP/FEIS.

Comments on the PRMP/FEIS should be sent to: District Manager, Bureau of Land Management, Salem District Office, 1717 Fabry Road SE, Salem, Oregon, 97306.

Protests should be sent to the Director (760), Bureau of Land Management, 1849 C Street N.W., Washington, D.C. 20240, within the 30-day protest period.

FOR FURTHER INFORMATION, CONTACT: Bob Saunders, RMP Team Leader, Salem District Office, Phone (503) 375–5634.

SUPPLEMENTARY INFORMATION: The PRMP/FEIS describes and analyzes seven alternatives which address the following issues/topics:

(1) timber production practices;

(2) old-growth forests and habitat diversity;

(3) threatened and endangered and other special status species habitat (including habitat for the northern spotted owl);

(4) special areas;

(5) visual resources;

(6) stream, riparian, and water quality;

(7) recreation resources;

(8) wild and scenic rivers;

(9) land tenure; and

(10) rural interface areas.

The PRMP/FEIS also incorporates the land use allocations and management direction from the 1994 Record of Decision for Amendments to Forest Service and Bureau of Land Management Planning Documents Within the Range of the Northern Spotted Owl (SEIS ROD).

In the BLM's proposed resource management plan, water quality would be maintained or improved primarily by a combination of best management practices and exclusion of selected areas from planned timber harvest. Particularly important exclusion areas would be riparian zones.

The major land use allocations of the proposed resource management plan are as follows: Late-Successional Reserves, 211,800 acres; Riparian Reserves, 221,800 acres (these are included within the other major land use allocations); Adaptive Management Area, 123,400 acres; General Forest Management Area, 107,300 acres; Connectivity/Diversity Blocks, 27,400 acres; and 7,900 acres of wilderness and a District-Designated Reserve.

In addition to protecting listed or proposed threatened and endangered species as required by the Endangered Species Act, the BLM would manage habitats of Federal candidate, State-listed, and Bureau-sensitive species to maintain their populations at a level that would avoid contributing to listing of the species. Additional species listed in the SEIS ROD would also be surveyed and managed.

Management would provide a wide variety of recreation opportunities, with particular emphasis on developed recreation sites, areas and trails, and outstanding natural areas.

Two river segments totaling 27.7 miles would be found suitable for designation by Congress as recreational river areas under the Wild and Scenic Rivers Act. Some 36.4 other miles of river determined eligible for designation and studied by the BLM would be found not suitable for designation.

Most BLM-administered lands with potential for occurrence would remain available for mineral leasing and location of mining claims, but 6,200 acres would be closed to leasing for oil and gas resources and 22,100 acres would be closed to location of claims.

The PRMP/FEIS proposes continuation of designation of 19 acres of critical environmental concern (ACEC) and designation of 9 new ACECs. The proposed resource management plan would redesignate or designate the following ACECs and one other special area with the noted restrictions.

PROPOSED SPECIAL AREAS

Name	Acres	Off-highway vehicle designation	Leasable mineral entry	Locatable/salable mineral entry	Timber harvest
A.J. Dwyer—Scenic Area	5	Limited	Open—NSO	Closed	No.
Carolyn's Crown—ACEC/RNA	261	Closed	Open—NSO	Closed	No.
Crabtree/Shafer Creek—ACEC/RNA/ONA	961.5	Limited	Open—NSO	Closed	No.
Elk Creek—ACEC	1,577	Closed	Open—NSO	Closed	No-Primary Zone. Yes-Secondary Zone.[1]
Forest Peak—ACEC/RNA	134	Closed	Open—NSO	Closed	No.
Grass Mtn.—ACEC/RNA	726	Closed	Open—NSO	Closed	No.
High Pk.-Moon Cr.—ACEC/RNA	1,538	Closed	Open—NSO	Closed	No.
Larch Mtn.—Env. Ed. Site	183	Closed	Open—NSO	Closed	No.
Little Grass Mtn.—ACEC/ONA	45	Closed	Open—NSO	Closed	No.
Little Sink—ACEC/RNA	81	Closed	Open—NSO	Closed	No.
Lost Prairie—ACEC	58	Closed	Open—NSO	Closed	No.
Marys Peak—ACEC/ONA	104	Limited	Open—NSO	Closed	No.
Middle Santiam—Terrace ACEC	108	Closed	Open—NSO	Closed	No.
Nestucca River—ACEC	1,062	Limited	Open—NSO	Closed	No.
North Santiam—ACEC	31	Closed	Open—NSO	Closed	No.
Rickreall Ridge—ACEC	177	Closed	Open—NSO	Closed	No.
Saddleback Mtn.—ACEC/RNA	151	Closed	Open—NSO	Closed	No.
Sandy River Gorge—ACEC/ONA	400	Closed	No	Closed	No.
Sheridan Peak—ACEC	299	Closed	Open—NSO	Open—AR	Yes.[1]
Soosap Meadows—ACEC	343	Closed	Open—NSO	Closed	No.
The Butte—ACEC/RNA	40	Closed	Open—NSO	Closed	No.
Valley of the Giants—ACEC/ONA	51	Closed	N/A[2]	N/A[2]	No.
Walker Flat—ACEC	10	Limited	Open—NSO	Closed	No.
White Rock Fen—ACEC	51	Closed	Open—NSO	Closed	No.
Wilhoit Spring—ACEC	170	Limited	Open—NSO	Closed	No Commercial Timber.
Willamette River—Parcels	76	Closed	Open—NSO	Closed	No Commercial Timber.
Williams Lake—ACEC	98	Limited	Open—NSO	Closed	No.
Yampo—ACEC	13	Limited	Open—NSO	Closed	No.
Yaquina Head—ACEC/ONA	106	Limited	Open—NSO	Closed	No Commercial Timber.

[1] Thinning in timber up to 110 years old.
[2] Mineral resources not federally administered.
ACEC=Area of Critical Environmental Concern
RNA=Research Natural Area
ONA=Outstanding Natural Area
NSO=No Surface Occupancy
AR=Additional restrictions
N/A=Not applicable

There are three potential ACEC areas identified that meet the Bureau criteria of relevance and importance but are not included in whole or in part in the PRMP/FEIS described above. One existing ACEC would not be redesignated because it does not meet ACEC criteria. The primary values of

these areas would be protected by other allocations.

This notice meets the requirements of 43 CFR 1610.7–2 for designation of ACECs and the requirements of the final revised Department of the Interior/ Department of Agriculture Guidelines for eligibility, Classification and Management of Rivers FR Vol. 47, No. 173, pg. 39454).

Dated: November 9, 1994.

Van W. Manning,

District Manager.

[FR Doc. 94–28872 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–33–P

[AZ–050–05–1210–04; AZA 25501]

Arizona: Muggins Mountains Wilderness; Implementation of Recreational Management Provisions in the Muggins Mountains Wilderness Management Plan

AGENCY: Bureau of Land Management, Interior.

ACTION: Closure of Muggins Mountains Wilderness to surface disturbing tools, equipment, and activities associated with recreational mineral extraction and hobby mineral collection.

SUMMARY: The Bureau of Land Management (BLM) Yuma District has initiated implementation of recreational management provisions of the Muggins Mountains Wilderness Management Plan which close the Muggins Mountains Wilderness to the use of dry washers, rocker boxes, and similar devices for recreational mineral extraction. Additionally, the closure prohibits the use of metal detectors and digging or prying tools such as shovels or rock hammers for hobby mineral collection. The closure is in effect until further notice and affects all of the Muggins Mountains Wilderness, 7710.98 acres more or less, as described by the Muggins Mountains Wilderness Boundary Map and BLM survey in Townships 7 and 8 South, Ranges 19 and 20 West, Gila and Salt River Meridian, Arizona. The BLM survey was completed on February 27, 1992 and accepted on April 10, 1992.

EFFECTIVE DATE: November 5, 1994.

FOR FURTHER INFORMATION CONTACT: Ron Morfin, Wilderness Specialist, Yuma Resource Area, 3150 Winsor Avenue, Yuma, Arizona 85365, telephone (602) 726–6300.

SUPPLEMENTARY INFORMATION: This action is authorized by Title 43, Code of Federal Regulations, Subpart 8560, Section 1–1 and is being taken to protect wilderness values. The action was called for in the Muggins Mountains Wilderness Management Plan which was available for a 30-day public review and comment period that ended on October 21, 1994.

Public notice of this action will be posted at the Yuma District Office, and at entry points to the Muggins Mountains Wilderness where activities affected by this notice have occurred. Violations of this order as provided for by Title 43, Code of Federal Regulations, Subpart 8560, Section 5, and Title 18, United States Code, Section 3571, are punishable by a fine not to exceed $100,000 for individuals and $200,000 for organizations and/or imprisonment not to exceed 12 months.

Dated: November 14, 1994.

Judith I. Reed,

District Manager.

[FR Doc. 94–28870 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–32–P

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, et seq.):

PRT–794720

Applicant: Circus Tihany, Sarasota, Florida

The applicant requests a permit to export one female Asian elephant (*Elephas maximus*) to Beto Carreiro World, Brazil, for the purpose of enhancement of survival through conservation education.

Applicant: Bobby Berosini, Ltd., Las Vegas, Nevada

PRT–79622

The applicant requests a permit to export and re-import four female and one male captive-bred orangutans (Pongo pygmaeus) to/from Televisa, Mexico City, Mexico, for the purpose of enhancement of survival of the species through conservation education.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 432, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act*, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 420(c), Arlington, Virginia 22203. Phone: (703/358–2104); FAX: (703/358–2281).

Dated: November 17, 1994.

Mary Ellen Amtower,

Acting Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 94–28863 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–55–P

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permits.

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Permit No. PRT–776608.

Applicant: Monk & Associates, Walnut Creek, California.

The applicant requests amendment of their permit to include take (harass by survey, collect and sacrifice voucher specimens) hatched individuals of the conservancy fairy shrimp (*Branchinecta conservatio*), longhorn fairy shrimp (*Branchinecta longiantenna*), and vernal pool tadpole shrimp (*Lepidurus packardi*) to determine presence or absence of the species in vernal pools throughout the species' range in California for the purpose of enhancement of survival of the species.

Permit No. PRT–787917.

Applicant: Earth Technology, Colton, California.

The applicant requests amendment of their permit to include take (harass by survey, collect and sacrifice voucher specimens) hatched individuals of the conservancy fairy shrimp (*Branchinecta conservatio*), longhorn fairy shrimp (*Branchinecta longiantenna*), Riverside fairy shrimp (*Streptocephalus wootoni*), and vernal pool tadpole shrimp (*Lepidurus packardi*) to determine presence or absence of the species in vernal pools at March Air Force Base, Riverside County, California for the purpose of enhancement of survival of the species.

Permit No. PRT–796280.

Applicant: Hydrozoology, Newcastle, California.

The applicant requests a permit to take (harass by survey, collect and sacrifice voucher specimens) eggs and hatched individuals of the conservancy fairy shrimp (*Branchinecta conservatio*), longhorn fairy shrimp (*Branchinecta longiantenna*), and vernal pool tadpole shrimp (*Lepidurus packardi*) to determine presence or absence of the species in vernal pools throughout the species' range in California for the purpose of enhancement of survival of the species.

Permit No. PRT–796282.

Applicant: Biosystems Analysis, Santa Cruz, California.

The applicant requests a permit to take (harass by survey, collect and sacrifice voucher specimens) eggs and hatched individuals of the conservancy fairy shrimp (*Branchinecta conservatio*), longhorn fairy shrimp (*Branchinecta longiantenna*), and vernal pool tadpole shrimp (*Lepidurus packardi*) to determine presence or absence of and conduct population analysis on the species in vernal pools throughout the species' range in California for the purpose of enhancement of survival of the species.

Permit No. PRT–796284

Applicant: Mr. Chris D. Rogers, Anderson, California.

The applicant requests a permit to take (harass by survey, collect and sacrifice voucher specimens) hatched individuals of the conservancy fairy shrimp (*Branchinecta conservatio*) to determine presence or absence of and conduct population analysis on the species in vernal pools throughout the species' range in California for the purpose of enhancement of survival of the species.

Permit No. PRT–796286.

Applicant: The Nature Conservancy, Tiburon, California.

The applicant requests a permit to take (harass by survey, collect and sacrifice voucher specimens) hatched individuals of the conservancy fairy shrimp (*Branchinecta conservatio*), longhorn fairy shrimp (*Branchinecta longiantenna*), Riverside fairy shrimp (*Streptocephalus wootoni*), and vernal pool tadpole shrimp (*Lepidurus packardi*) to determine presence or absence of the species in vernal pools throughout the species' range in California for the purpose of enhancement of survival of the species.

Permit No. PRT–796288.

Applicant: California Department of Transportation, Sacramento, California.

The applicant requests a permit to take (harass by survey, collect and sacrifice voucher specimens) eggs and hatched individuals of the conservancy fairy shrimp (*Branchinecta conservatio*), longhorn fairy shrimp (*Branchinecta longiantenna*), Riverside fairy shrimp (*Streptocephalus wootoni*), and vernal pool tadpole shrimp (*Lepidurus packardi*) to determine presence or absence of the species in vernal pools throughout the species' range in California for the purpose of enhancement of survival of the species.

DATES: Written comments on the permit applications must be received by December 23, 1994.

ADDRESSES: Written data or comments should be submitted to the Chief, Division of Consultation and Conservation Planning, Ecological Services, U.S. Fish and Wildlife Service, 911 N.E. 11th Avenue, Portland, Oregon 97232–4181. Please refer to the respective permit number for each application when submitting comments.

FOR FURTHER INFORMATION CONTACT: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents, within 30 days of the date of publication of this notice, to the following office: Division of Consultation and Conservation Planning, Ecological Services, U.S. Fish and Wildlife Service, 911 N.E. 11th Avenue, Portland, Oregon 97232–4181. Telephone: 503–231–2063; FAX: 503–231–6243. Please refer to the respective permit number for each application when requesting copies of documents.

Dated: November 14, 1994.

William F. Shake,

Acting Deputy Regional Director, Region 1, Portland, Oregon.

[FR Doc. 94–28871 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–55–P

National Park Service

Notice of Inventory Completion for Native American Human Remains From the Island of Molokai, HI, in the Possession of the Los Angeles County Museum of Natural History

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003(d), of completion of the inventory of Native American human remains from the island of Molokai, HI, that are presently in the possession of the Los Angeles County Museum of Natural History.

A detailed inventory and assessment of these human remains has been made by Los Angeles County Museum of Natural History curatorial staff in consultation with representatives of *Hui Mālama I Nā Kūpuna 'O Hawai'i Nei.*

The human remains consist of two human teeth and two fragments of human teeth. The human remains were donated to the Los Angeles County Museum of Natural History in 1927 by Dr. William A. Bryan, Director, Los Angeles County Museum. The human remains were catalogued into the museum as A.1463.27–36 with the description: "box of human teeth from the battle field of Momumi."

Inventory of the human remains and review of accompanying documentation indicate that no known individuals were identifiable. A representative of *Hui Mālama I Nā Kūpuna 'O Hawai'i Nei* has identified "Momumi" as the site of Mo'omomi on the island of Molokai and stated that the sand dunes of Mo'omumi have long been used as burial grounds for ancestral Native Hawaiians. Reference to the "battlefield of Momumi" is thought to refer to this burial area. The representative of *Hui Mālama I Nā Kūpuna 'O Hawai'i Nei* has also provided documentation that shows that Bryan and others collected human remains from Mo'omumi.

Based on the above mentioned information, officials of the Los Angeles County Museum of Natural History have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity which can be reasonably traced between these human remains and present-day Native Hawaiian organizations.

This notice has been sent to officials of *Hui Mālama I Nā Kūpuna 'O Hawai'i Nei*, the Office of Hawaiian Affairs, and the Molokai Island Burial Council, all of which qualify as Native Hawaiian organizations as defined by 25 U.S.C. 3001 (11). Representatives of any other Native Hawaiian organization which believes itself to be culturally affiliated with these human remains should contact Dr. Margaret Ann Hardin, Curator and Section Head, Anthropology, Los Angeles County Museum of Natural History, 900 Exposition Boulevard, Los Angeles, CA 90007; telephone: (213) 744–3382, before December 23, 1994. Repatriation of these human remains to *Hui Mālama I Nā Kūpuna 'O Hawai'i Nei* may begin after that date if no additional claimants come forward.

Dated: November 15, 1994.

Francis P. McManamon,

Departmental Consulting Archeologist, Chief, Archeological Assistance Division.

[FR Doc. 94–28903 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–70–F

Notice of Intent to Repatriate a Cultural Item in the Possession of the Metropolitan Museum of Art, New York

AGENCY: National Park Service, Interior

ACTION: Notice

Act of 1990 of the intent to repatriate a cultural item in the possession of the Metropolitan Museum of Art that meets the definitions of "sacred object" and "object of cultural patrimony" under section 2 of the act.

The carved wooden figure measures 29 3/4 inches high. The figure was donated by Mr. Raymond Weilgus in 1964 to the Museum of Primitive Art. The figure was transferred to the Metropolitan Museum of Art in 1978. Museum records do not indicate where or when the object was originally collected.

Information regarding the carved wooden figure was included in the summary sent to the Pueblo of Zuni in November, 1993. A representative of the Pueblo of Zuni subsequently requested additional documentation of the figure, including museum records and a photograph. Representatives of the Pueblo of Zuni have inspected the museum records and the photograph and have identified the carved wooden figure as being a *Ahayu:da* or War God. The Pueblo of Zuni affirms that this *Ahayu:da* is needed by traditional Zuni religious leaders for the practice of traditional Zuni religion by present-day adherents. The Pueblo of Zuni also affirms that this *Ahayu:da* is of ongoing importance to the pueblo as a whole and could not have been alienated, appropriated, or conveyed by any individual member of the Pueblo of Zuni.

Based on the above mentioned information, officials of the Metropolitan Museum of Art have determined that,

pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity which can be reasonably traced between the figure and the Pueblo of Zuni. Officials of the Metropolitan Museum of Art have also determined that the figure meets the definitions of sacred object and object of cultural patrimony pursuant to 25 U.S.C. 3001 (3)(C).

Representatives of any other Indian tribe that believes itself to be culturally affiliated with this object should contact Julie Jones, Curator in Charge, Department of the Arts of Africa, Oceania, and the American, Metropolitan Museum of Art, 1000 5th Avenue, NY, NY 10028–1098, telephone: (212) 570– 3705 before December 23, 1994. Repatriation of the object to the Pueblo of Zuni can begin after that date if no additional claimants come forward.

Dated: November 16, 1994.

Dr. Francis P. McManamon,

Departmental Consulting Archeologist, Chief, Archeological Assistance Division.

[FR Doc. 94–28901 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–70–F

Notice of Inventory Completion for Native Hawaiian Remains From Sunset Beach, North Shore of Oahu, HI, in the Possession of the University of Alaska Museum, University of Alaska Fairbanks, in Fairbanks, AK

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is hereby given under the Native American Graves Protection and Repatriation Act of 1990 of the completion of inventory of human remains under Section 2 of the act in the possession of the University of Alaska Museum, University of Alaska Fairbanks.

The human remains consist of a cranium and mandible collected at Sunset Beach, North Shore of Oahu, Hawaii by Margaret MacMahon Ellis in 1948. Accession records indicate that the human remains were donated to the University of Alaska Museum on May 1, 1949 by Mrs. Ellis and are identified as Accession 422, Catalog 16–1.

The human remains represent an adult of unknown sex. There are no morphological features evident that would suggest that the human remains are anything other than those of a Native Hawaiian. Based on the above information the University of Alaska Museum Curatorial Staff believes that a relationship of shared group identity can be reasonably traced between the human remains and the descendants of the aboriginal people who, prior to 1778, occupied and exercised sovereignty in the area that now constitutes the State of Hawai'i.

The cranium was repatriated in May, 1991, to representatives of *Hui Mālama I Nā Kūpuna 'O Hawai'i Nei.* The articulating mandible, which could not be located at that time, has since been found. Representatives of culturally affiliated Native Hawaiian organizations are advised that the mandible has been transferred to representatives of *Hui Mālama I Nā Kūpuna 'O Hawai'i Nei.* Representatives of any other Native Hawaiian organization that believes itself to be culturally affiliated with this mandible should contact: Gary M. Selinger, University of Alaska Museum, University of Alaska Fairbanks, Fairbanks, AK 99775, telephone: (907) 474–6117; and Kunani Nihipali, *Hui Mālama I Nā Kūpuna 'O Hawai'i Nei,* P.O. Box 190, Hale'iwa, HI 96712–0190 telephone: (808) 587–0010, by December 23, 1994. Reinternment of the mandible by *Hui Mālama I Nā Kūpuna 'O Hawai'i Nei* may begin after that date if no additional claimants come forward.

Dated: November 15, 1994.

Francis. P. McManamon,

Departmental Consulting Archeologist, Chief, Archeological Assistance Division.

[FR Doc. 94–28902 Filed 11–22–94; 8:45 am]

BILLING CODE 4310–70–F

INTERSTATE COMMERCE COMMISSION

[Docket No. AB–240 (Sub–No. 4X)]

Cambria and Indiana Railroad Company; Abandonment Exemption; Cambria County, PA

Cambria and Indiana Railroad Company (C&I) has filed a notice of exemption under 49 CFR Part 1152 Subpart F—Exempt Abandonments to abandon: (1) A 4.20-mile segment of its Main Line between milepost 2.099 at Clover and milepost 6.299 at Holman in Cambria, Barr, and Blacklick Townships, Cambria County, PA; and (2) a 13.129-mile segment of its Cambria Branch between milepost 0.00 at its intersection with the Main Line at Main Line station 5.453 and milepost 13.129 in Nanty-Glo and Revloc Boroughs, and Cambria and Blacklick Townships, in Cambria County, PA.

C&I has certified that: (1) No local traffic has moved over the line for at least 2 years;[1] (2) there is no overhead traffic on the line; (3) no formal complaint filed by a user of rail service on the line (or by a State or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or with any U.S. District Court or has been decided in favor of the complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (service of environmental

[1] On November 14, 1994, C&I clarified its certification and advised the Commission that a one-time shipment of eight cars of construction materials that moved to C&I's material yard were non-revenue loads.

report on agencies), 49 CFR 1105.8 (service of historic report on State Historic Preservation Officer), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication),[2] and 49 CFR 1152.50(d)(1) (service of verified notice on governmental agencies) have been met.

As a condition to use of this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on December 23, 1994, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[3] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[4] and trail use/rail banking requests under 49 CFR 1152.29[5] must be filed by December 5, 1994. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by December 13, 1994, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any pleading filed with the Commission should be sent to applicant's representative: Joseph M. O'Malley, 1170 Eighth Avenue, Bethlehem, PA 18016.

If the notice of exemption contains false or misleading information, the exemption is void *ab initio*.

[2] C&I originally filed this notice of exemption under Docket No. AB–240 (Sub–No. 3X). However, by decision served September 27, 1994, the Commission's Section of Environmental Analysis found that the environmental report was inadequate and did not contain an historic report. The notice of exemption was rejected. C&I refiled its notice on November 3, 1994. Notice of publication appeared in the Johnstown Tribune-Democrat, Johnstown, PA, on August 31, 1994, under Docket No. AB–240 (Sub–No. 3X).

[3] A stay will be issued routinely by the Commission in those proceedings where an informed decision on environmental issues (whether raised by a party or by the Commission's Section of Environmental Analysis in its independent investigation) cannot be made prior to the effective date of the notice of exemption. See *Exemption of Out-of-Service Rail Lines*, 5 I.C.C.2d 377 (1989). Any entity seeking a stay on environmental concerns is encouraged to file its request as soon as possible in order to permit the Commission to review and act on the request before the effective date of this exemption.

[4] See Exempt. of Rail Abandonment—Offers of Finan. Assist., 4 I.C.C.2d 164 (1987).

[5] The Commission will accept a late-filed trail use request as long as it retains jurisdiction to do so.

C&I has filed an environmental report which addresses the abandonment's effects, if any, on the environment and historic resources. The Section of Environmental Analysis (SEA) will issue an environmental assessment (EA) by November 28, 1994. Interested persons may obtain a copy of the EA by writing to SEA (Room 3219, Interstate Commerce Commission, Washington, DC 20423) or by calling Elaine Kaiser, Chief of SEA, at (202) 927–6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: November 15, 1994.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 94–28904 Filed 11–22–94; 8:45 am]

BILLING CODE 7035–01–P

[Finance Docket No. 32609]

Chesapeake Railroad Company—Modified Rail Certificate

On October 28, 1994, Chesapeake Railroad Company (CHRR) filed a notice for a modified certificate of public convenience and necessity under 49 CFR 1150, Subpart C, to operate a line of railroad between milepost 00.0 at Clayton, DE, and milepost 45.3 at Easton, MD, and a connecting branch line between milepost 00.0 at Queen Anne, MD, and milepost 8.8 at Denton, MD, a total distance of approximately 54.1 miles.

The lines were owned by the Trustees of the former Penn Central Transportation Company. The Trustees abandoned the lines in 1976 pursuant to Section 304 of the Regional Rail Reorganization Act of 1973.[1] On January 8, 1982, the Trustees sold the lines to the State of Maryland Department of Transportation, Mass Transit Administration (MTA). MTA has entered into an operating agreement with CHRR.

The Commission will serve a copy of this notice on the Association of American Railroads (Car Service Division), as agent of all railroads subscribing to the car-service and car-hire agreement, and on the American Short Line Railroad Association.

Decided: November 16, 1994.

[1] Pub. L. 93–236, 87 Stat. 1008, codified at 45 U.S.C. 744.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 94–28905 Filed 11–22–94; 8:45 am]

BILLING CODE 7035–01–P

DEPARTMENT OF JUSTICE

Information Collections Under Review

The Office of Management and Budget (OMB) has been sent the following collection(s) of information proposals for review under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35) and the Paperwork Reduction Reauthorization Act since the last list was published. Entries are grouped into submission categories, with each entry containing the following information:

(1) The title of the form/collection;

(2) The agency form number, if any, and the applicable component of the Department sponsoring the collection;

(3) How often the form must be filled out or the information is collected;

(4) Who will be asked or required to respond, as well as a brief abstract;

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond;

(6) An estimate of the total public burden (in hours) associated with the collection; and,

(7) An indication as to whether Section 3504(h) of Public Law 96–511 applies.

Comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the OMB reviewer, Mr. Jeff Hill on (202) 395–7340 and to the Department of Justice's Clearance Officer, Mr. Robert B. Briggs, on (202) 514–4319. If you anticipate commenting on a form/collection, but find that time to prepare such comments will prevent you from prompt submission, you should notify the OMB reviewer and the Department of Justice Clearance Officer of your intent as soon as possible. Written comments regarding the burden estimate or any other aspect of the collection may be submitted to Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, and to Mr. Robert B. Briggs, Department of Justice Clearance Officer, Systems Policy Staff/Information Resources Management/Justice Management Division, Suite 850, WCTR, Washington, DC 20530.

Extension of the Expiration Date of a Currently Approved Collection Without Any Change in the Substance or in the Method of Collection

(1) Certification of Identity.

(2) JMD Form 361. Justice Management Division.

(3) On occasion.

(4) Individuals or households, State or local governments, Farms, Businesses or other for-profit, Federal agencies or employees, Non-profit institutions, Small businesses or organizations. This form is used to identify individuals requesting certain records under the Privacy Act. Without this form an individual cannot obtain the information requested.

(5) 34,390 annual respondents at 1 hour per response.

(6) 34,390 annual burden hours.

(7) Not applicable under Section 3504(h) of Public Law 96–511.

Public comment on this item is encouraged.

Dated: November 17, 1994.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 94–28875 Filed 11–22–94; 8:45 am]

BILLING CODE 4410–26–M

Foreign Claims Settlement Commission

Claims Against Islamic Republic of Iran; Request for Current Addresses

AGENCY: Foreign Claims Settlement Commission of the United States, Justice.

ACTION: Notice.

SUMMARY: The persons listed at the end of this notice have claims pending against the Islamic Republic of Iran which are before the Foreign Claims Settlement Commission (FCSC) for adjudication as authorized under Title V of the Foreign Relations Authorization Act, Fiscal Years 1986 and 1987 (Pub.L. 99–93, approved August 16, 1985, 99 Stat. 437 (50 U.S.C. 1701 note); the "Iran Claims Act"), and the *Settlement Agreement in Claims of Less than $250,000, Case No. 86 and Case No. B38*, Award No. 483 (1990); the "Settlement Agreement"). However, these persons have failed to inform the FCSC of their current addresses. The claims of the persons listed at the end of this notice will be dismissed by the FCSC, unless current addresses are provided to the FCSC by [*enter date 30 days after date of publication of this notice*].

DATES: The deadline for providing an updated address is December 23, 1994. Send the updated address to the person in **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: David E. Bradley, Chief Counsel, Foreign Claims Settlement Commission of the United States, 600 E Street, N.W., Room 6002, Washington, DC 20579, (202) 616–6975, FAX (202) 616–6993.

David E. Bradley,

Chief Counsel.

Name and last known address of claimant	Claim No.
George W. Harvey, 855 Garfield Ave., Lansdale, PA 19446.	IR–1326.
Madeline P. Stephens, 8407 Hanbridge Lane, Austin, TX 78736.	IR–1805.
James Griffin, 1304 N. Highway 360, Apt. 205, Grand Prairie, TX 75050.	IR–2825.

[FR Doc. 94–28876 Filed 11–22–94; 8:45 am]

BILLING CODE 4410–01–P

DEPARTMENT OF LABOR

Employment and Training Administration

Job Training Partnership Act: Employment and Training Assistance for Dislocated Workers; Reallotment of Title III Funds

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The Department of Labor is publishing for public information the Job Training Partnership Act Title III (Employment and Training Assistance for Dislocated Workers) funds identified by States for reallotment, and the amount to be reallotted to eligible States.

FOR FURTHER INFORMATION CONTACT: Mr. Eric Johnson, Office of Worker Retraining and Adjustment Programs, Employment and Training Administration, Department of Labor, Room N–5426, 200 Constitution Avenue NW., Washington, D.C. 20210. Telephone: 202–219–5577 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Pursuant to Title III of the Job Training Partnership Act (JTPA or the Act), as amended by the Economic Dislocation and Worker Adjustment Assistance Act (EDWAA), the Secretary of Labor (Secretary) is required to recapture funds from States identified pursuant to section 303(b) of the Act, and reallot such funds by a Notice of Obligation (NOO) adjustment to current year funds to "eligible States" and "eligible high unemployment States", as set forth in section 303 (a), (b), and (c) of JTPA. 29 U.S.C. 1653. The basic reallotment process was described in Training and Employment Guidance Letter No. 4–88, dated November 25, 1988, Subject: Reallotment and Reallocation of Funds under Title III of the Job Training Partnership Act (JTPA), as amended, 53 FR 43737 (December 2, 1988). The reallotment process for Program Year (PY) 1994 funds was described in Training and Employment Guidance Letter No. 4–93, dated January 27, 1994, Subject: Reallotment of Job Training Partnership Act (JTPA) Title III Formula-Allotted Funds.

NOO adjustments to the PY 1994 (July 1, 1994–June 30, 1995) formula allotments are being issued based on expenditures reported to the Secretary by the States, as required by the recapture and reallotment provisions at Section 303 of JTPA. 29 U.S.C. 1653.

The funds recaptured are an amount equal to the sum of every State's unexpended PY 1993 formula funds in excess of 20 percent of its PY 1993 formula allotments, and all unexpended funds made available by formula for PY 1992. A State's PY 1993 formula allotments include the initial allotment for PY 1993, and any additional funds received by the State during the PY 1993 reallotment process. Funds are recaptured from PY 1994 formula allotments, and are distributed by formula to eligible States and eligible high unemployment States, resulting in either an upward or downward adjustment to every State's PY 1994 allotment.

Unemployment Data

The unemployment data used in the formula for reallotments, relative numbers of unemployed and relative numbers of excess unemployed, were for the September 1993 through August 1994 period. Long-term unemployment data used were for calendar year 1993. The determination of "eligible high unemployment States" for the reallotment of excess unexpended funds was also based on unemployment data for the period September 1993 through August 1994, with all average unemployment rates rounded to the nearest tenth of one percent. The unemployment data were provided by the Bureau of Labor Statistics, based upon the Current Population Survey.

The table below displays the distribution of the net changes to PY 1994 formula allotments.

U.S. DEPARTMENT OF LABOR—EMPLOYMENT AND TRAINING ADMINISTRATION, PY 1994 JTPA TITLE III REALLOTMENT TO STATES

	Col 1	Col 2	Col 3	Col 4	Col 5	Col 6
Alabama	6.8	137,151	103,238	103,238	39,726	5,813
Alaska	8.0	1,252	20,823	20,823	8,013	27,584
Arizona	5.8	518,060	72,386	0	27,854	(490,206)
Arkansas	5.6	46,183	0	0	0	(46,183)
California	9.0	0	1,329,303	1,329,303	511,522	1,840,825
Colorado	5.1	3,840	55,849	0	21,491	17,651
Connecticut	5.4	0	77,001	0	29,630	29,630
Delaware	5.3	0	12,528	0	4,821	4,821
District of Columbia	8.5	0	25,434	25,434	9,787	35,221
Florida	6.7	2,019,459	346,563	346,563	133,359	(1,539,537)
Georgia	5.8	0	143,331	0	55,154	55,154
Hawaii	4.9	0	13,850	0	5,330	5,330
Idaho	5.2	0	17,674	0	6,801	6,801
Illinois	6.2	0	296,219	0	113,986	113,986
Indiana	5.1	0	83,013	0	31,944	31,944
Iowa	3.7	7,490	26,102	0	10,044	2,554
Kansas	5.3	13,410	0	0	0	(13,410)
Kentucky	5.3	0	60,921	0	23,443	23,443
Louisiana	7.8	0	121,840	121,840	46,885	168,725
Maine	7.4	0	41,908	41,908	16,126	58,034
Maryland	5.7	0	114,433	0	44,034	44,034
Massachusetts	6.3	0	166,989	0	64,258	64,258
Michigan	6.6	0	232,214	232,214	89,357	321,571
Minnesota	4.2	0	55,652	0	21,415	21,415
Mississippi	6.6	524,066	0	0	0	(524,066)
Missouri	5.5	0	97,667	0	37,583	37,583
Montana	5.2	0	13,496	0	5,193	5,193
Nebraska	2.7	0	8,887	0	3,420	3,420
Nevada	6.1	0	34,809	0	13,395	13,395
New Hampshire	5.3	0	24,601	0	9,467	9,467
New Jersey	7.0	0	251,161	251,161	96,648	347,809
New Mexico	6.1	0	34,204	0	13,162	13,162
New York	7.4	0	581,033	581,033	223,584	804,617
North Carolina	4.3	6,452	68,594	0	26,395	19,943
North Dakota	4.2	0	5,632	0	2,167	2,167
Ohio	6.1	0	255,621	0	98,364	98,364
Oklahoma	6.3	0	68,622	0	26,406	26,406
Oregon	6.3	0	74,003	0	28,477	28,477
Pennsylvania	6.4	0	299,943	0	115,419	115,419
Puerto Rico	15.4	2,861,725	0	0	0	(2,861,725)
Rhode Island	7.6	0	35,514	35,514	13,666	49,180
South Carolina	6.8	0	101,775	101,775	39,163	140,938
South Dakota	3.0	0	4,232	0	1,629	1,629
Tennessee	5.1	0	69,235	0	26,642	26,642
Texas	6.7	0	466,646	466,646	179,568	646,214
Utah	3.5	3,034	13,612	0	5,238	2,204
Vermont	4.7	0	9,240	0	3,556	3,556
Virginia	5.0	0	84,340	0	32,454	32,454
Washington	6.6	145,085	139,977	139,977	53,864	48,756
West Virginia	9.9	0	80,611	80,611	31,020	111,631
Wisconsin	4.6	0	53,887	0	20,736	20,736
Wyoming	6.0	16,547	9,141	0	3,518	(13,029)
National total	6.5	6,303,754	6,303,754	3,878,040	2,425,714	0

Explanation of Table

Column 1: This column shows each State's unemployment rate for the twelve months ending August 1994.

Column 2: This column shows the amount of excess funds (unexpended PY 1993 funds in excess of 20 percent of the State's PY 1993 formula allotments as described above and/or unexpended PY 1992 formula-allotted funds), which are subject to reallotment. PY 1994 funds in an amount equal to the excess funds identified will be recaptured from such States and distributed as discussed below.

Column 3: This column shows total excess funds distributed among all "eligible States" by applying the regular Title III formula. "Eligible States" are those with unexpended PY 1993 funds at or below the level of 20 percent of their PY 1993 formula allotments as described above.

Column 4: Eligible States with unemployment rates higher than the national average, which was 6.5 percent for the 12-month period, are "eligible high unemployment States." These eligible high unemployment States received amounts equal to their share of the excess funds (the amounts shown in column 3) according to the regular Title III formula. This is Step 1 of the reallotment process. These amounts are

shown in column 4 and total $3,878,040.

Column 5: The sum of the remaining shares of available funds ($2,425,714) for eligible States with unemployment rates less than or equal to the national average is distributed among all eligible States, again using the regular Title III allotment formula. This is Step 2 of the reallotment process. These amounts are shown in column 5.

Column 6: Net changes in PY 1994 formula allotment are presented. This column represents the decreases in Title III funds shown in column 2, and the increases in Title III funds shown in columns 4 and 5. NOOs in the amounts shown in column 6 are being issued to the States listed.

Equitable Procedures

Pursuant to section 303(d) of the Act, Governors of States required to make funds available for reallotment shall prescribe equitable procedures for making funds available from the State and substate grantees. 29 U.S.C. 1653(d).

Distribution of Funds

Funds are being reallotted by the Secretary in accordance with section 303 (a), (b), and (c) of the Act, using the factors described in section 302(b) of the Act. 29 U.S.C. 1652(b) and 1653 (a), (b), and (c). Distribution within States of funds allotted to States shall be in accordance with section 302 (c) and (d) of the Act (29 U.S.C. 1652 (c) and (d)), and the JTPA regulation at 20 CFR 631.12(d).

Signed at Washington, D.C., this 17th day of November, 1994.

Doug Ross,

Assistant Secretary of Labor.

[FR Doc. 94-28931 Filed 11-22-94; 8:45 a.m.]

BILLING CODE 4510-30-M

Occupational Safety and Health Administration

Advisory Committee on Construction Safety and Health; Full Committee Meeting

Notice is hereby given that the Advisory Committee on Construction Safety and Health, established under section 107(e)(1) of the Contract Work Hours and Safety Standards Act (40 U.S.C. 333) and section 7(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 656), will meet on December 8–9, 1994 at the Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue, NW., Room C–5521/5523, Washington, DC. The meetings of the full Committee and the work groups are open to the public and will begin at 9 a.m. on each day. On December 9, the meeting will conclude at approximately 3:00 p.m.

At this meeting, OSHA will brief the Advisory Committee regarding the relationship between the generic fall protection standard (subpart M) and the steel erection standard (subpart R); the standards planning process; and the activities of OSHA's Office of Construction and Engineering. In addition, the Committee will discuss the Construction Safety Excellence Program. On December 8, the work groups on Hexavalent Chromium, Gender Issues, and Recordkeeping & Targeting will meet, based in Room C–5521/5523, from approximately 2:00 to 5:00 p.m. Those work groups will report back to the full Committee on December 9 and the full Committee will discuss the reports from the work groups.

Written data, views or comments may be submitted, preferably with 20 copies, to the Division of Consumer Affairs, at the address provided below. Any such submissions received prior to the meeting will be provided to the members of the Committee and will be included in the record of the meeting. Anyone wishing to make an oral presentation should notify the Division of Consumer Affairs before the meeting. The request should state the amount of time desired, the capacity in which the person will appear and a brief outline of the content of the presentation. Persons who request the opportunity to address the Advisory Committee may be allowed to speak, as time permits, at the discretion of the Chairman of the Advisory Committee. Individuals with disabilities who wish to attend the meeting should contact Tom Hall, at the address indicated below, if special accommodations are needed.

For additional information contact: Holly Nelson, Office of the Assistant Secretary, Room S–2316, Telephone 202–219–6027; or Tom Hall, Division of Consumer Affairs, Room N–3647, Telephone 202–219–8615, at the Occupational Safety and Health Administration, 200 Constitution Avenue, NW., Washington, DC, 20210. An official record of the meeting will be available for public inspection at the OSHA Docket Office, Room N–2625, Telephone 202–219–7894.

Signed at Washington, D.C. this 11 day of November 1994.

Joseph A. Dear,

Assistant Secretary of Labor.

[FR Doc. 94-28930 Filed 11-22-94; 8:45 am]

BILLING CODE 4510-26-M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–352 and 50–353]

Philadelphia Electric Company; Limerick Generating Station, Units 1 and 2; Notice of Issuance of Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of amendments to Facility Operating Licenses Nos. NPF–39 and NPF–85, issued to Philadelphia Electric Company (PECo or the licensee), for the operation of the Limerick Generating Station, Units 1 and 2, located in Montgomery County, Pennsylvania.

Identification of Proposed Action

The amendment would consist of changes to the Technical Specifications (TSs) and would authorize an increase of the storage capacity in each of the spent fuel pools (SFP) from 2040 fuel assemblies to 4117 fuel assemblies.

The amendment to the TS is responsive to the licensee's application dated January 14, 1994. The NRC staff has prepared an Environmental Assessment of the Proposed Action.

Summary of Environmental Assessment

The "Final Generic Environmental Impact Statement (FGEIS) on Handling and Storage of Spent Light Water Power Reactor Fuel," NUREG–0575, Volumes 1–3, concluded that the environmental impact of interim storage of spent fuel was negligible. Because of the differences in design, the FGEIS recommended licensing SFP expansions on a case-by-case basis.

For Limerick, 1 and 2, the expansion of the storage capacity of the SFP will not create any significant additional radiological effects or nonradiological environmental impacts. The additional whole body dose that might be received by an individual at the site boundary and the estimated dose to the population within an 80 kilometer radius is believed to be too small to have any significance when compared to the fluctuations in the annual dose this population receives from exposure to background radiation. The occupational radiation dose for the proposed operation of the expanded SFP is estimated to be extremely small compared to the total annual occupational radiation exposure for this facility.

The nonradiological impacts of SFP expansion include increased heat load due to the increased spent fuel inventory and a corresponding increase

in spent fuel waste heat rejected from the plant. The total increase in heat load is well within the plant cooling system capability and the additional waste heat rejected to the environment will be small in comparison to the amount of total heat currently being released. There is no significant environmental impact attributed to the waste heat from the plant due to this very small increase.

Finding of No Significant Impact

The staff has reviewed the proposed SFP expansion to the facility relative to the requirements set forth in 10 CFR part 51. Based upon the environmental assessment, the NRC staff concludes that there are no significant radiological or nonradiological impacts associated with the proposed license amendment and that the issuance of the proposed license amendment will have no significant impact on the quality of the human environment. Therefore, the Commission has determined, pursuant to 10 CFR 51.31, not to prepare an environmental impact statement for the proposed amendment.

For further details with respect to this action, see (1) the application for amendments dated January 14, 1994, and supplements dated March 22, July 14, September 1, and October 21, 1994, (2) the FGEIS on Handling and Storage of Spent Light Water Power Reactor Fuel (NUREG–0575), (3) the Final Environmental Statement for the Limerick Generating Station, Units 1 and 2, dated April 1984, and (4) the Environmental Assessment, dated November 16, 1994.

These documents are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Pottstown Public Library, 500 High Street, Pottstown, Pennsylvania 19464.

Dated at Rockville, Maryland, this 16th day of November 1994.

For the Nuclear Regulatory Commission.

John F. Stolz,

Director, Project Directorate I–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 94–28909 Filed 11–22–94; 8:45 am]

BILLING CODE 7590–01–M

Licensing Support System Advisory Review Panel

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

The Licensing Support System Advisory Review Panel (LSSARP) will hold a meeting on December 12 and 13, 1994, at the Yucca Mountain Site Characterization Project Office, Room 450, Bank of America Building, 101 Convention Center Drive, Las Vegas, Nevada. The entire meeting will be open to the public pursuant to the Federal Advisory Committee Act (Pub. L. 94–463, 86 Stat. 770–776).

The Nuclear Regulatory Commission (NRC) established the LSSARP in 1989 to provide advice and recommendations to the NRC and to the Department of Energy (DOE) on topics, issues, and activities related to the design, development and operation of an electronic information management system known as the Licensing Support System (LSS). This system will contain information relevant to the Commission's future licensing proceeding for a geologic repository for the disposal of high-level radioactive waste. Membership on the Panel consists of representatives of the State of Nevada, a coalition of affected units of local Government in Nevada, the National Congress of American Indians, a coalition of organizations representing the nuclear industry, DOE, NRC and other agencies of the Federal government which have experience with large electronic information management systems.

The meeting will begin at 8:30 a.m. on both days. The agenda will consist of briefings and discussions on the following topics:

1. DOE's Reevaluation of LSS Concept
2. Overview of Optical Character Recognition Work at the University of Nevada-Las Vegas
3. NRC oversight of LSS Operations
4. Establishment of a Technical Working Group for the Panel
5. Use of LSS on Pilot Project Basis.

On the afternoon of December 13, interested Panel Members will be provided a demonstration of OCR technology research at the University of Nevada-Las Vegas.

Interested persons may make oral presentations to the Panel or file written statements. Requests for oral presentations should be made to the contact person listed below as far in advance as practicable so that appropriate arrangements can be made.

For further information regarding this meeting contact John C. Hoyle, Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555: telephone 301–504–1969.

Dated: November 17, 1994.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 94–28913 Filed 11–22–94; 8:45 am]

BILLING CODE 7590–01–M

Biweekly Notice

Applications and Amendments to Facility Operating LicensesInvolving No Significant Hazards Considerations

I. Background

Pursuant to Public Law 97–415, the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. Public Law 97–415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from October 31, 1994, through November 10, 1994. The last biweekly notice was published on November 9, 1994 (59 FR 55865).

Notice Of Consideration Of Issuance Of Amendments To Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, And Opportunity For A Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that

failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

By December 23, 1994, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC and at the local public document room for the particular facility involved. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to (**Project Director**): petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for a hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's

Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room for the particular facility involved.

Carolina Power & Light Company, Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of amendment request: August 11, 1994

Description of amendment request: The proposed amendment deletes the requirement to perform a five-year interval hydrostatic test on the auxiliary coolant system critical headers from Technical Specification Section 4.1.3, Table 4.1–3, Item 11.

Basis for proposed no significant hazards consideration determination:

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated. The proposed change will delete the requirement to perform a hydrostatic test on the component cooling water [CCW] system at five year intervals to ensure the integrity of the system. However, adequate testing of the system is provided as required by the ASME Code Section XI. This testing includes a 10-year system hydrostatic test as well as a 40-month interval system inservice test and provides assurance of system integrity and the ability to perform the intended function. Therefore, there is no increase in the probability or consequences of an accident previously evaluated.

2. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed change will delete the requirement to perform a hydrostatic test on the component cooling water system at five-year intervals to ensure the integrity of the associated system headers. Operating characteristics of the system and its physical configuration will remain unchanged, and the system will continue to perform its intended function. There will be an overall decrease in the frequency of testing the CCW system due to the elimination of redundant testing and a decrease in operational activity associated with testing the CCW system. Since there will be no functional or hardware changes to the system, the proposed change will not create the possibility of a new or different type of accident.

3. The proposed amendment does not involve a significant reduction in the margin of safety. The proposed change will delete the requirement to perform a hydrostatic test on the component cooling water system at five-year intervals to ensure the integrity of the system. However, adequate testing of the system is ensured by the required ASME Code Section XI tests. This testing includes a 10-year system hydrostatic test as well as a 40-month interval system inservice test and provides assurance of system integrity and the ability to perform the intended function. Therefore, there will be no reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Hartsville Memorial Library, 147 West College Avenue, Hartsville, South Carolina 29550

Attorney for licensee: R. E. Jones, General Counsel, Carolina Power & Light Company, Post Office Box 1551, Raleigh, North Carolina 27602

NRC Project Director: William H. Bateman

Carolina Power & Light Company, et al., Docket No. 50-400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

Date of amendment request: October 24, 1994

Description of amendment request: The proposed amendment would remove Technical Specifications (TS) 3.3.4, Turbine Overspeed Protection; TS 3.7.12, Area Temperature Monitoring; and TS 3.11.2.6, Gas Storage Tanks; and their associated bases; and relocate them to licensee-controlled documents, such as the Final Safety Analysis Report.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes will simplify the TS, and implement the recommendations of the Commission's Final Policy Statement on TS Improvements. Since the elements of these TS are being relocated to licensee-controlled documents any future changes would be controlled under 10 CFR 50.59. The proposed changes are administrative in nature and do not involve any modifications to any plant equipment or affect plant operation. Therefore, there would be no increase in the probability or consequences of an accident previously evaluated.

2. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes are administrative in nature, do not involve any physical alterations to plant equipment, and result in no change in the method by which any safety-related system performs its function. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed amendment does not involve a significant reduction in the margin of safety.

These changes do not affect any Final Safety Analysis Report (FSAR) Chapter 15 accident analyses or have any impact on margin as defined in the Bases to the Technical Specifications. Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Cameron Village Regional Library, 1930 Clark Avenue, Raleigh, North Carolina 27605

Attorney for licensee: R. E. Jones, General Counsel, Carolina Power & Light Company, Post Office Box 1551, Raleigh, North Carolina 27602

NRC Project Director: William H. Bateman

Florida Power and Light Company, et al., Docket Nos. 50–335 and 50–389, St. Lucie Plant, Unit Nos. 1 and 2, St. Lucie County, Florida

Date of amendment request: October 27, 1994

Description of amendment request: The proposed amendments will improve consistency throughout the Technical Specifications and their related Bases by removing outdated material and blank pages, incorporating minor changes in text, making editorial corrections, and resolving other inconsistencies identified by the plant operations staff.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Pursuant to 10 CFR 50.92, a determination may be made that a proposed license amendment involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. Each standard is discussed as follows:

(1) Operation of the facility in accordance with the proposed amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed amendments consist of administrative changes to the Technical Specifications (TS) for St. Lucie Units 1 and 2. The amendments will update the index and remove blank pages; implement minor changes in text to rectify reference, nomenclature, spelling, and/or consistency-in-format errors; and otherwise improve consistency within the TS for each unit. The proposed amendments do not involve changes to the configuration or method of operation of plant equipment that is used to mitigate the consequences of an accident, nor do the changes otherwise affect the initial conditions or conservatisms assumed in any of the plant accident analyses. Therefore, operation of the facility in accordance with the proposed amendments would not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Operation of the facility in accordance with the proposed amendment would not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed administrative revisions will not change the physical plant or the modes of plant operation defined in the Facility License for each unit. The changes do not involve the addition or modification of equipment nor do they alter the design or operation of plant systems. Therefore, operation of the facility in accordance with the proposed amendments would not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) Operation of the facility in accordance with the proposed amendment would not involve a significant reduction in a margin of safety.

The proposed amendments are administrative in nature and do not change the basis for any technical specification that is related to the establishment of, or the preservation of, a nuclear safety margin. Therefore, operation of the facility in accordance with the proposed amendments would not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Indian River Junior College Library, 3209 Virginia Avenue, Fort Pierce, Florida 34954-9003

Attorney for licensee: Harold F. Reis, Esquire, Newman and Holtzinger, 1615 L Street, NW., Washington, DC 20036

NRC Project Director: Mohan C. Thadani, Acting

Florida Power and Light Company, Docket Nos. 50–250 and 50–251, Turkey Point Plant Units 3 and 4, Dade County, Florida

Date of amendment request: October 20, 1994.

Description of amendment request: This supersedes the licensee's original request dated July 19, 1994, and Noticed in the **Federal Register** on August 3, 1994 (59 FR 39587). The licensee proposes to change Turkey Point Units 3 and 4 Technical Specifications and its associated BASES, which address the maximum allowed reactor thermal power operation with inoperable main steam safety valves (MSSVs). Westinghouse issued Nuclear Safety Advisory Letter 94-001 which notified the licensee of a deficiency in the basis of the Turkey Point Technical Specification 3/4.7.1, which allows the plant to operate at reduced power levels with a specified number of MSSVs inoperable. This amendment request corrects the allowable power level with inoperable MSSVs and revises the TS to conform with the guidelines of the standard technical specifications.

The licensee also proposed changes to TS 4.7.1.1 to indicate that the provisions of TS 4.0.4 are not applicable for entry into mode 3.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Operation of the facility in accordance with the proposed amendments would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated. The proposed maximum allowable power level values will ensure that the secondary side steam pressure will remain below 110 percent of the design value following a Loss of Load/Turbine Trip event, when one or more main steam safety valves (MSSVs) are declared inoperable. The proposed change will not impact the classification of the Loss of Load/Turbine Trip event as a Condition II probability event (faults of moderate frequency) per ANSI—N18.2, 1973. Accordingly, since the proposed maximum allowable power level will maintain the capability of the MSSVs to perform their pressure relief function associated with a Loss of Load/Turbine Trip event, there will be no effect on the probability or consequences of an accident previously evaluated.

The proposed addition of ACTION statement [a] to TS 3.7.1.1, will not [a]ffect the probability or consequences of an accident previously evaluated, since the proposed action is consistent with the current Technical Specifications. Reducing the Power Range Neutron Flux High Trip Setpoint to the maximum power level will ensure the energy transfer to the most limiting steam generator is not greater than the available relief capacity in that steam generator. Entry into mode 3 does not require the availability of the MSSV, since plant conditions (i.e., not operating at reactor power) do not create the possibility of a secondary side overpressurization event.

In addition, the proposed change to Surveillance Requirement 4.7.1.1, will not [a]ffect the probability or consequences of an accident previously evaluated, since the proposed plant condition is an analyzed shutdown condition. Entry into Mode 3 for surveillance testing does not require the availability of the MSSV, since plant conditions (i.e., not operating at reactor power) do not create the possibility of a secondary side overpressurization event.

(2) Operation of the facility in accordance with the proposed amendments would not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed changes do not involve any change to the configuration of any plant equipment, and no new failure modes have been defined for any plant system or component. The proposed maximum allowable power level will maintain the capability of the MSSVs to perform their pressure relief function to ensure the secondary side steam design pressure is not exceeded following a Loss of Load/Turbine Trip event. Therefore, since the function of the MSSVs is unaffected by the proposed changes, the possibility of a new or different kind of accident from any accident previously evaluated is not created.

The proposed addition of ACTION statement [a] to TS 3.7.1.1, will not create the possibility of a new or different kind of accident from any accident previously evaluated, since the proposed action is consistent with the current Technical Specifications. Reducing the Power Range Neutron Flux High Trip Setpoint to the maximum power level will ensure the energy transfer to the most limiting steam generator is not greater than the available relief capacity in that steam generator. Entry into mode 3 does not require the availability of the MSSV, since plant conditions (i.e., not operating at reactor power) do not create the possibility of a secondary side overpressurization event.

In addition, the proposed change to Surveillance Requirement 4.7.1.1, will not create the possibility of a new or different kind of accident from any accident previously evaluated, since the proposed plant condition is an analyzed shutdown condition. Entry into Mode 3 for surveillance testing does not require the availability of the MSSV, since plant conditions (i.e., not operating at reactor power) do not create the possibility of a secondary side overpressurization event.

(3) Operation of the facility in accordance with the proposed amendments would not

involve a significant reduction in a margin of safety.

The proposed changes to the Technical Specifications do not involve a significant reduction in a margin of safety. The algorithm methodology used to calculate the maximum allowable power level is conservative and bounding since it is based on a number of inoperable MSSVs per loop; i.e., if only one MSSV in one loop is out of service, the required action to reduce power to the maximum allowable power level would be the same as if one MSSV in each loop were out of service. Another conservatism with the algorithm methodology is with the assumed minimum total steam flow rate capability of the operable MSSVs. The assumption is that if one or more MSSVs are inoperable per loop, the inoperable MSSVs are the largest capacity MSSVs, regardless of which capacity MSSVs are actually inoperable. Therefore, since the maximum allowable power level calculated for the proposed changes using the algorithm methodology are more conservative and ensure the secondary side steam design pressure is not exceeded following a Loss of Load/Turbine Trip event, this proposed license amendment will not involve a significant reduction in a margin of safety.

The proposed addition of ACTION statement [a] to TS 3.7.1.1, will not involve a significant reduction in a margin of safety, since the proposed action is consistent with the current Technical Specifications. Reducing the Power Range Neutron Flux High Trip Setpoint to the maximum power level will ensure the energy transfer to the most limiting steam generator is not greater than the available relief capacity in that steam generator. Entry into mode 3 does not require the availability of the MSSV, since plant conditions (i.e., not operating at reactor power) do not create the possibility of a secondary side overpressurization event.

In addition, the proposed change to Surveillance Requirement 4.7.1.1, will not involve a significant reduction in the margin of safety, since the proposed plant condition is an analyzed shutdown condition. Entry into Mode 3 for surveillance testing does not require the availability of the MSSV, since plant conditions (i.e., not operating at reactor power) do not create the possibility of a secondary side overpressurization event.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Florida International University, University Park, Miami, Florida 33199

Attorney for licensee: Harold F. Reis, Esquire, Newman and Holtzer, P.C., 1615 L Street, NW., Washington, DC 20036

NRC Project Director: Mohan C. Thadani, (Acting)

Florida Power and Light Company, Docket Nos. 50–250 and 50–251, Turkey Point Plant Units 3 and 4, Dade County, Florida

Date of amendment request: October 20, 1994

Description of amendment request: The licensee proposes to change Turkey Point Units 3 and 4 Technical Specifications (TS) by removing the schedule for the withdrawal of reactor vessel material surveillance specimens. The control of changes to this schedule, by way of a license amendment to modify the TS, duplicates the requirements of Section II.B.3 of Appendix H to Part 50 of Title 10 of the Code of Federal Regulations (10 CFR). These proposed license amendments are consistent with the guidance provided to licensees by NRC Generic Letter (GL) 91-01, "Removal of the Schedule for the Withdrawal of Reactor Vessel Material Specimens from Technical Specifications." Additionally, these amendments propose to correct typographical errors in the TS BASES and to revise the reference in the TS BASES to the American Society for Testing and Materials (ASTM) standard by which the fracture toughness properties of the ferritic materials in the reactor vessels are determined.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Operation of the facility in accordance with the proposed amendments would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed license amendments do not involve a change in the probability or consequences of accidents previously evaluated since no physical changes to the plant, their operation, nor their procedures are involved. The proposed changes are administrative in nature and involve the activity of relocating, from the Turkey Point Units 3 and 4 Technical Specifications (TS) to the Updated Final Safety Analysis Report (UFSAR), the schedule for the withdrawal of reactor vessel material surveillance specimens. The control of changes to this schedule, by way of a license amendment to modify the TS, duplicates the requirements of Section II.B.3 of Appendix H to Part 50 of Title 10 of the Code of Federal Regulations (10 CFR). These proposed license amendments are consistent with the guidance provided to licensees by NRC Generic Letter (GL) 91-01, "Removal of the Schedule for the Withdrawal of Reactor Vessel Material Specimens from Technical Specifications." The TS BASES are also revised to remove references to the table being removed from the TS. In accordance with GL 91–01, FPL commits to maintain, the NRC-approved version of the specimen withdrawal schedule in the Turkey Point Units 3 and 4 UFSAR.

The current Turkey Point Units 3 and 4 TS BASES provide background information on the use of the data obtained from material specimens. This background information clearly defines the purpose and relationship of this information to the requirements included in the regulations and the ASME Code. Therefore, the removal of the schedule for specimen withdrawal from the TS will not result in any relaxation of the regulatory requirements of Appendix H to 10 CFR Part 50 and do not involve an increase in the probability or consequences of an accident previously evaluated.

The typographical corrections in the TS BASES and the revision to the reference to ASTM E–185 are consistent with the guidance for implementing administrative corrections to the TS to ensure that references in the TS BASES are proper and correct.

In summary, operation of the facility in accordance with the proposed amendment would not involve an increase in the probability or consequences of an accident previously evaluated.

(2) Operation of the facility in accordance with the proposed amendments would not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed license amendments do not create the possibility of a new or different kind of accident from any accident previously evaluated since no physical changes to the plant, their operation, nor procedures are involved. The proposed changes are administrative in nature and involve the activity of relocating, from the Turkey Point Units 3 and 4 Technical Specifications (TS) to the UFSAR, the schedule for the withdrawal of reactor vessel material surveillance specimens. The control of changes to this schedule, by way of a license amendment to modify the TS, duplicates the requirements of Section II.B.3 of Appendix H to Part 50 of Title 10 of the Code of Federal Regulations (10 CFR). These proposed license amendments are consistent with the guidance provided to licensees by NRC GL 91–01, "Removal of the Schedule for the Withdrawal of Reactor Vessel Material Specimens from Technical Specifications." The TS Bases are also revised to remove references to the table being removed from the TS.

The removal from the TS of the schedule for the withdrawal of reactor vessel material surveillance specimens will not result in any loss of regulatory control because changes to this schedule are controlled by the requirements of Appendix H to 10 CFR Part 50. In addition, to ensure that the surveillance specimens are withdrawn at the proper time, Surveillance Requirement 4.4.9.1.2 indicates that the specimens shall be removed and examined to determine changes in their material properties, as required by Appendix H. In accordance with GL 91–01, FPL commits to maintain, the NRC-approved version of the specimen withdrawal schedule in the Turkey Point Units 3 and 4 UFSAR.

The typographical corrections in the TS BASES and the revision to the reference to ASTM E–185 are consistent with the guidance for implementing administrative corrections to the TS to ensure that references in the TS BASES are proper and correct.

The current Turkey Point Units 3 and 4 TS BASES provide background information on the use of the data obtained from material specimens. This background information clearly defines the purpose and relationship of this information to the requirements included in the regulations and the ASME Code. Therefore, the removal of the schedule for specimen withdrawal from the TS will not result in any relaxation of the regulatory requirements of Appendix H to 10 CFR Part 50 and would not create the possibility of a new or different kind of accident from any accident previously evaluated.

3) Operation of the facility in accordance with the proposed amendments would not involve a significant reduction in a margin of safety.

The proposed license amendments do not involve physical changes to the plant, their operation, nor their procedures. The proposed license amendments do not create the possibility of a new or different kind of accident from any accident previously evaluated since no physical changes to the plant, their operation, nor their procedures are involved. The proposed changes are administrative in nature and involve the activity of relocating, from the Turkey Point Units 3 and 4 Technical Specifications (TS) to the UFSAR, the schedule for the withdrawal of reactor vessel material surveillance specimens. The control of changes to this schedule, by way of a license amendment to modify the TS, duplicates the requirements of Section II.B.3 of Appendix H to Part 50 of Title 10 of the Code of Federal Regulations (10 CFR). These proposed license amendments are consistent with the guidance provided to licensees by NRC GL 91–01, "Removal of the Schedule for the Withdrawal of Reactor Vessel Material Specimens from Technical Specifications." The TS Bases are also revised to remove references to the table being removed from the TS.

The removal from the TS of the schedule for the withdrawal of reactor vessel material surveillance specimens will not result in any loss of regulatory control because changes to this schedule are controlled by the requirements of Appendix H to 10 CFR Part 50. In addition, to ensure that the surveillance specimens are withdrawn at the proper time, Surveillance Requirement 4.4.9.1.2 indicates that the specimens shall be removed and examined to determine changes in their material properties, as required by Appendix H. In accordance with GL 91–01, FPL commits to maintain the NRC-approved version of the specimen withdrawal schedule in the Turkey Point Units 3 and 4 UFSAR.

The typographical corrections in the TS BASES and the revision to the reference to ASTM E–185 are consistent with the guidance for implementing administrative corrections to the TS to ensure that references in the TS BASES are proper and correct.

The current Turkey Point Units 3 and 4 TS BASES provide background information on the use of the data obtained from material specimens. This background information clearly defines the purpose and relationship of this information to the requirements included in the regulations and the ASME Code. Therefore, the removal of the schedule for specimen withdrawal from the TS will not result in any relaxation of the regulatory requirements of Appendix H to 10 CFR Part 50 and would not involve a reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Florida International University, University Park, Miami, Florida 33199

Attorney for licensee: Harold F. Reis, Esquire, Newman and Holtzer, P.C., 1615 L Street, NW., Washington, DC 20036

NRC Project Director: Mohan C. Thadani, (Acting)

Niagara Mohawk Power Corporation, Docket No. 50-410, Nine Mile Point Nuclear Station, Unit 2, Oswego County, New York

Date of amendment request: October 28, 1994

Description of amendment request: The proposed amendment would revise Technical Specification (TS) 1.7, "CORE ALTERATION," to indicate that movement or replacement of incore instrumentation is not considered to be a CORE ALTERATION provided that there are no fuel assemblies in the associated core cell. TS 3/4.9.3, "Control Rod Position," and associated Bases would be revised to be consistent with the proposed revision of TS 1.7 by changing the requirement to verify that all control rods be inserted only during loading of fuel assemblies into the core rather than during CORE ALTERATIONS. The licensee has stated that these proposed changes are consistent with the NRC's "Improved Standard Technical Specifications," (NUREG–1434) and those to be incorporated in Revision 1.The proposed amendment would also revise Item 1.i.3) of TS Tables 3.3.2–1 and 4.3.2.1–1 to delete the requirement showing that the Standby Liquid Control System (SLCS) initiates Reactor Water Cleanup (RWCU) isolation in OPERATIONAL CONDITION 5. License Amendment No. 48 issued on September 30, 1993, deleted the requirement for SLCS to be OPERABLE in OPERATIONAL CONDITION 5 but due to an oversight, failed to delete item 1.i.3) and associated notations from TS Tables 3.3.2–1 and 4.3.2.1–1. The proposed amendment would correct this oversight.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The purpose of the definition of CORE ALTERATION is to identify operations which have the potential for adding reactivity to the core while the vessel head is removed and fuel is in the vessel. The proposed definition of CORE ALTERATION explicitly states that movement of incore instruments and undervessel replacement is not considered to be a CORE ALTERATION. The amount of fissile material contained in any of these instruments is insignificant and thus would not result in any change in reactivity of the core. Similarly, control rod movement with no fuel assemblies in the associated core cell has negligible impact on the reactivity of the remaining core. Removal of a control rod by either the normal control rod drive system or uncoupling and removing the blade from the top of the vessel with no fuel in the associated cell is not considered a CORE ALTERATION. It has negligible impact on the reactivity of the remaining core and is not required to be covered by Specification 3/4.9.3. In addition, the drop of a blade on irradiated fuel is bounded by the fuel bundle drop.

The proposed change to Specification 3/4.9.3, "Control Rod Position," making it applicable only during loading of fuel assemblies to reflect the remaining condition that results in the addition of positive reactivity. Specification 3/4.9.1, "Reactor Mode Switch," requires the mode switch be locked in the refuel position. This initiates the one-rod-out interlock which prevents the selection of more than one control rod for movement. Specification 3/4.1.1, "Shutdown Margin," requires shutdown margin be greater than or equal to 0.38% delta k/k analytically determined or 0.28% delta k/k determined by test. These specifications ensure that the reactor will not become critical when all control rods are not inserted. Removal of the note referencing Special Test Exemption 3.10.3 is to be consistent with the revised definition.

The proposed change to eliminate RWCU isolation requirement upon initiation of SLCS in OPERATIONAL CONDITION 5 is consistent with Amendment 48, which eliminated the requirement for SLCS to be OPERABLE in OPERATIONAL CONDITION 5.

Therefore, these changes will not involve a significant increase in the probability or consequences of an accident from any previously evaluated.

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes to the definition of CORE ALTERATION and Specification 3/4.9.3, "Control Rod Position," and deletion of the RWCU isolation requirement on SLCS initiation in OPERATIONAL CONDITION 5 do not involve a physical change in any system's configuration. Systems required to be OPERABLE for CORE ALTERATIONS are still required to be OPERABLE, however, no new modes of operation are introduced based on the proposed definition.

The purpose of the definition of CORE ALTERATION is to identify operations which have the potential for adding reactivity to the core while the vessel head is removed and fuel is in the vessel. The proposed definition of CORE ALTERATION explicitly states that movement of incore instruments and undervessel replacement is not considered to be a CORE ALTERATION. The amount of fissile material contained in any of these instruments is insignificant and thus would not result in any change in reactivity of the core. Similarly, control rod movement with no fuel assemblies in the associated core cell has negligible impact on the reactivity of the remaining core. Removal of a control rod by either the normal control rod drive system or uncoupling and removing the blade from the top of the vessel with no fuel in the associated cell is not considered a CORE ALTERATION. It has negligible impact on the reactivity of the remaining core and is not required to be covered by Specification 3/4.9.3. In addition, the drop of a blade on irradiated fuel is bounded by the fuel bundle drop.

The proposed change to Specification 3/4.9.3, "Control Rod Position," making it applicable only during loading of fuel assemblies to reflect the remaining condition which results in the addition of positive reactivity. Specification 3/4.9.1, "Reactor Mode Switch," requires the mode switch be locked in the refuel position. This initiates the one-rod-out interlock which prevents the selection of more than one control rod for movement. Specification 3/4.1.1, "Shutdown Margin," requires shutdown margin be greater than or equal to 0.38% delta k/k analytically determined or 0.28% delta k/k determined by test. These specifications ensure that the reactor will not become critical when all control rods are not inserted. Removal of the note referencing Special Test Exemption 3.10.3 is to be consistent with the revised definition.

The proposed change to eliminate RWCU isolation requirement upon initiation of SLCS in OPERATIONAL CONDITION 5 is consistent with Amendment 48, which eliminated the requirement for SLCS to be OPERABLE in OPERATIONAL CONDITION 5.

Therefore, these changes will not create the possibility of a new or different kind of accident from any previously evaluated.

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not involve a significant reduction in the margin of safety.

The proposed definition of CORE ALTERATION clearly details what constitutes a CORE ALTERATION. The definition is consistent with NUREG-1433, "Improved Standard Technical Specifications." The definition has no impact on safety limits, setpoints, or plant design and thus does not affect a margin of safety.

The proposed change to Specification 3/4.9.3, "Control Rod Position," making it applicable only during loading of fuel assemblies to reflect the remaining condition that results in the addition of positive reactivity. Specification 3/4.9.1, "Reactor Mode Switch," requires the mode switch be locked in the refuel position. This initiates the one-rod-out interlock which prevents the selection of more than one control rod for movement. Specification 3/4.1.1, "Shutdown Margin," requires shutdown margin be greater than or equal to 0.38% delta k/k analytically determined or 0.28% delta k/k determined by test. These specifications ensure that the reactor will not become critical when all control rods are not inserted, thus does not affect a margin of safety. The removal of the note referencing Special Test Exemption 3.10.3 is consistent with the revised definition.

Elimination of the requirement to initiate RWCU isolation based upon SLCS initiation in OPERATIONAL CONDITION 5 is consistent with deletion of the requirement to have the SLCS OPERABLE during OPERATIONAL CONDITION 5. Therefore, there is no impact on a margin of safety.

Therefore, based upon the above, these proposed changes will not involve a significant reduction [in] a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston & Strawn, 1400 L Street, NW., Washington, DC 20005-3502.

NRC Project Director: Michael J. Case, Acting

Northeast Nuclear Energy Company (NNECO), Docket No. 50–245, Millstone Nuclear Power Station, Unit 1, New London County, Connecticut

Date of amendment request: October 4, 1994

Description of amendment request: The proposed amendment relocates the primary containment isolation valve list from Technical Specification (TS) Section 3.7.D to the Millstone Unit 1 technical requirements manual (TRM). This change is in accordance with the guidance of Generic Letter (GL) 91–08. The proposed amendment also makes administrative and editorial changes to TS Section 3.7.D and makes changes to the associated bases.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

NNECO has reviewed the proposed change in accordance with 10 CFR 50.92 and concluded that the change does not involve a significant hazards consideration (SHC). The basis for this conclusion is that the three criteria of 10 CFR 50.92(c) are not compromised. The proposed change does not involve a significant hazards consideration because the change would not:

1. Involve a significant increase in the probability or consequences of an accident previously analyzed.

The proposed change will not result in any hardware or operating changes. The proposed change is based upon Generic Letter 91–08 and merely removes the containment isolation valve table and all references to the table. The removal of the isolation valve table from the technical specifications does not affect the operability requirements of any of the listed valves. The technical specifications will continue to require the isolation valves to be OPERABLE. LCO's [limiting condition for operation] and surveillance requirements for the valves will also remain in the technical specifications. The containment isolation valve table will be relocated to the Millstone Unit No. 1 TRM which is controlled in accordance with 10 CFR 50.59.

This change is administrative in nature and does not involve an increase in the probability or consequence of an accident previously evaluated. Further, the proposed change does not alter the design, function, or operation of the valves involved, and therefore does not affect the probability or consequence of any previously evaluated accident.

The clarification of Surveillance Requirement 4.7.D.2 ensures that the flow path affected by an inoperable primary containment isolation valve is isolated and maintained in the isolated condition. This change ensures that probability or consequence of a previously analyzed accident is not increased.

The nonintent changes involved with this license amendment request are administrative in nature and will not, in and of themselves, increase the probability or consequences of any transient or accident previously analyzed. This does not affect or have any potential impact upon any of the design basis types of accidents previously analyzed. There are no failure modes affected by the changes. As such, there are no design basis accidents affected by the changes.

2. Create the possibility of a new or different kind of accident from any previously analyzed.

The proposed change will not impose any different operational or surveillance

requirements, nor will the change remove any such requirements. The change proposes to relocate the containment isolation valve list from the technical specifications to the TRM. Adequate control of information is maintained. Further, as stated above, the proposed change does not alter the design, function, or operation of the valves involved, and therefore no new accident scenarios are created.

The clarification of Surveillance Requirement 4.7.D.2 ensures that the flow path affected by an inoperable primary containment isolation valve is isolated and maintained in the isolated condition. Since this change only ensures that the position of a valve in the isolated condition is recorded, this change cannot create a new or different kind of accident.

The nonintent changes do not, by their nature, modify plant response during operation or during any transient or accident. Therefore, there are no failure modes that can represent a new unanalyzed accident.

3. Involve a significant reduction in the margin of safety.

The proposed change will not reduce the margin of safety since it has no impact on any safety analysis assumption. The proposed change does not decrease the scope of equipment currently required to be operable or subject to surveillance testing, nor does the proposed change affect any instrument setpoints or equipment safety functions.

The relocation of the valve list is consistent with the guidance provided in GL 91–08. The intent of the technical specification will be met since the change will not alter function or operability requirements for any primary containment isolation valve.

The clarification of Surveillance Requirement 4.7.D.2 ensures that the flow path affected by an inoperable primary containment isolation valve is isolated and maintained in the isolated condition. Therefore, this change ensures that the margin of safety established by the safety analyses is maintained.

The nonintent changes involved with this license amendment request are administrative in nature and will not, in and of themselves, reduce any margin of safety. There is no impact on the performance of any safety system. There is no increase in the consequences of any accident and, as such, there is no reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Learning Resource Center, Three Rivers Community-Technical College, Thames Valley Campus, 574 New London Turnpike, Norwich, CT 06360.

Attorney for licensee: Ms. L. M. Cuoco, Senior Nuclear Counsel, Northeast Utilities Service Company, Post Office Box 270, Hartford, CT 06141-0270.

NRC Project Director: Phillip F. McKee

Northeast Nuclear Energy Company, et al., Docket No. 50-423, Millstone Nuclear Power Station, Unit No. 3, New London County, Connecticut

Date of amendment request: September 28, 1994

Description of amendment request: The proposed change would revise the Surveillance Requirement 4.6.1.2.a of the Technical Specifications to permit a more flexible schedule for containment leakage Type A testing. The information in the associated Bases Section would also be changed. In conjunction with this amendment request, the licensee has requested a partial and schedular exemption, dated September 28, 1994, from the requirements of Section III.D.1.(a) of Appendix J to Title 10 of the Code of Federal Regulations, Part 50.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

...The basis for this conclusion is that the three criteria of 10 CFR 50.92(c) are not compromised. The proposed change does not involve a SHC [significant hazards consideration] because the change would not:

Involve a significant increase in the probability or consequences of an accident previously analyzed.

Type A tests are performed to ensure that the total leakage from containment does not exceed the maximum allowable primary containment leakage rate at a calculated peak containment internal pressure permitted by the Millstone Unit No. 3 Technical Specifications and FSAR [Final Safety Analysis Report]. This assures compliance with the dose limits of 10CFR100.

The proposed change to Surveillance Requirement 4.6.1.2.a of the Millstone Unit No. 3 Technical Specifications will increase the flexibility for scheduling the Type A tests. They do not modify the maximum allowable leakage rate at the calculated peak containment pressure, do not impact the design basis of the containment, and do not change the post-accident containment response.

The first two Type A tests of the first 10-year service period for Millstone Unit No. 3 have been conducted. The results of these tests demonstrate that Millstone Unit No. 3 has maintained control of containment integrity by maintaining margin between the acceptance criterion and the "As-Found" and "As-Left" leakage rates.

Historically, Type A tests have a relatively low failure rate, where Type B and C testing (local leakage rate tests) could not detect the leakage path. Most Type A test failures are attributed to failures of Type B or C components (containment penetrations and isolation valves). Type B and C components are tested per Surveillance Requirement 4.6.1.2.d of the Millstone Unit No. 3 Technical Specifications. These tests are required to be conducted at intervals no greater than 24 months, and the acceptance criterion for the combined leakage rate for all penetrations and valves subject to the Type B and C tests is 0.6 L_a. These local leakage rate tests provide assurance that containment integrity is maintained. The relatively low "As-Left" Type B and C total leakage resulting from each successive outage indicates that the leakage has been maintained within the technical specification acceptance criterion, and demonstrates that improvements are continually being made to the Type B and C program. The Type B and C leakage results have decreased over the last three refueling outages. This proposal does not request any changes to the requirements for Type B and C testing. The Type B and C tests will continue to be performed in accordance with the requirements of Surveillance Requirement 4.6.1.2.d. These tests confirm that the leak-tightness of the containment isolation valves and penetrations has been maintained.

Based on the previous Type A, B, and C tests, the Millstone Unit No. 3 containment's structural integrity is considered to be in sound condition. No operations are known to have occurred which would suggest any substantial degradation of these results. Additionally, no structural modifications are planned for the next refueling outage.

Based on the above, the proposed change to Surveillance Requirement 4.6.1.2.a of the Millstone Unit No. 3 Technical Specifications does not involve a significant increase in the probability or consequences of an accident previously analyzed.

2. Create the possibility of a new or different kind of accident from any previously analyzed.

The proposed change to Surveillance Requirement 4.6.1.2.a of the Millstone Unit No. 3 Technical Specifications will increase the flexibility in scheduling the Type A tests. They do not make any physical or operational changes to existing plant structures, systems, or components. In addition, the proposed change does not modify the acceptance criteria for the Type A tests. Maintaining the leakage through the containment boundary to the atmosphere within a specific value ensures that the plant complies with the requirements of 10 CFR 100. The containment boundary serves as an accident mitigator; it is not an accident initiator. Therefore, the proposed change to Surveillance Requirement 4.6.1.2.a does not create the possibility of a new or different kind of accident from any previously analyzed.

3. Involve a significant reduction in the margin of safety.

The proposed change to Surveillance Requirement 4.6.1.2.a of the Millstone Unit No. 3 Technical Specifications will increase the flexibility for scheduling the Type A tests. They do not modify the maximum allowable leakage rate at the calculated peak containment pressure, do not impact the design basis of the containment, and do not

change the post-accident containment response.

Based on the previous Type A, B, and C tests, the Millstone Unit No. 3 containment's structural integrity is considered to be in sound condition. No operations are known to have occurred which would suggest any substantial degradation of these results. Additionally, no structural modifications are planned for the next refueling outage.

Based on the above, the proposed change does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Learning Resource Center, Three Rivers Community-Technical College, Thames Valley Campus, 574 New London Turnpike, Norwich, CT 06360.

Attorney for licensee: Ms. L. M. Cuoco, Senior Nuclear Counsel, Northeast Utilities Service Company, Post Office Box 270, Hartford, CT 06141–0270.

NRC Project Director: Phillip F. McKee

Public Service Electric & Gas Company, Docket Nos. 50–272 and 50–311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of amendment request: September 29, 1994

Description of amendment request: The proposed change would remove the sections from the Techical Specifications that are entitled "Seismic Instrumentation" and "Meteorological Instrumentation" and relocate the information and testing requirements to the Salem Updated Final Safety Analysis Report. The proposed change conforms with the NRC guidance presented in the "Final Policy Statement on Technical Specifications Improvements for Nuclear Power Reactors" published in the Federal Register (58 FR 39132).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes involve no hardware changes, no changes to the operation of any systems or components, and no changes to existing structures. Neither the relocation of the seismic/meteorological specifications to the Salem UFSAR nor the elimination of the Special Report requirements represent changes that affect plant safety or alter existing accident analyses.

2. Will not create the possibility of a new or different kind of accident from any previously evaluated.

The proposed changes are procedural in nature concerning the operability and surveillance of instrumentation that are not safety related and will not impact the operation of any plant safety related component or equipment. Therefore, these changes will not create a new or unevaluated accident or operating condition.

3. Will not involve a significant reduction in a margin of safety.

In accordance with guidance provided by the NRC regarding the improvement of Technical Specifications (58 FR 39132), the proposed changes relocate the seismic and meteorological instrumentation portion of the Technical Specification, with the exception of the Special Report requirements, to the Salem UFSAR. These instruments are not safety related and do not have any associated safety margins which could be affected by this change.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Salem Free Public library, 112 West Broadway, Salem, New Jersey 08079

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston and Strawn, 1400 L Street, NW, Washington, DC 20005-3502

NRC Project Director: John F. Stolz

Public Service Electric & Gas Company, Docket Nos. 50-272 and 50-311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of amendment request: September 29, 1994

Description of amendment request: The proposed change to the Technical Specifications revises the surveillance interval for performing an air or smoke flow test through each containment spray header from once every five years to once every ten years. The proposed change implements a recommended line-item improvement from Generic Letter 93-05, "Line-Item Technical Specifications Improvements to Reduce Surveillance Requirements for Testing During Power Operation."

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change does not affect the assumptions, design parameters or results of UFSAR accidents analyzed. The proposed change does not involve a hardware change, a change to the operation of any system or component, or a change to an existing structure. The proposed change leads to a reduction in radiation exposure to plant personnel and the reduction of an unnecessary burden on plant staff. The Containment Spray System header and nozzles are fabricated from corrosion resistant stainless steel and are maintained dry. Operating experience demonstrates that the proposed increase in the Containment Spray surveillance test interval would not affect operability of the system. Testing the Containment Spray System header and nozzles at the proposed increased surveillance interval does not increase the probability or consequences of an accident previously evaluated.

2. Does not create the possibility of a new or different kind of accident from any previously evaluated.

The proposed change does not modify equipment, affect the system design basis or operability. This change does not alter parameters utilized in the analyzed accident scenarios. The Containment Spray System piping and nozzles are fabricated from corrosion resistant stainless steel. The proposed change in surveillance frequency is consistent with the guidance provided in GL 93-05. Testing the Containment Spray System header and nozzles at the proposed increased surveillance interval does not create the possibility of a new of different kind of accident from those previously evaluated.

3. Does not involve a significant reduction in a margin of safety.

The proposed change only involves a decrease in the surveillance frequency and does not alter the performance of the surveillance itself. System equipment and operation remains unchanged. Operability and reliability is still maintained by periodic testing. Testing the Containment Spray System header and nozzles at the proposed increased surveillance interval does not involve a significant reduction in the margins of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Salem Free Public library, 112 West Broadway, Salem, New Jersey 08079

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston and Strawn, 1400 L Street, NW, Washington, DC 20005-3502

NRC Project Director: John F. Stolz

Public Service Electric & Gas Company, Docket Nos. 50–272 and 50–311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of amendment request: October 11, 1994

Description of amendment request: The proposed amendment would make two Technical Specification changes concerning the pressurizer heaters. The first change would add the phrase "capable of being powered from an emergency power supply" to the Limiting Condition of Operation (LCO) 3/4.4.4. The second change would alter the frequency of surveillance requirement 4.4.4.2 from 92 days to every refueling outage.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

0. Does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The request (both proposed changes) does not change any assumption or parameter assumed to function in any of the design/licensing basis analysis.

The proposed change as described in section IA merely relocates the requirement to supply emergency power to the required heater group from the action to the LCO statement.

The change as described in section IB does not eliminate the surveillance requirement, but extends its frequency from 92 days to once per refueling outage in accordance with NRC recommendation. The design of the Salem Station Pressurizer heaters is identical to that described in the NUREG 1366 (Improvements to Technical Specifications Surveillance Requirements, published December 1992), and Generic Letter 93-05 (Line-Item Technical Specifications improvements to Reduce Surveillance Requirements for Testing During Power Operation, issued on September 27, 1993), and the extension of the surveillance requirement is a recognized enhancement and assurance to the continued reliability of the pressurizer heaters.

Based upon the above, PSE&G concludes that the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.2. Does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes do not introduce any design or physical configuration changes to the facility which could create new accident scenarios.

3. Does not involve a significant reduction in a margin of safety.

As stated in response to question number 1 above, the request does not change any assumption or parameter assumed to function in any of the design/licensing basis analysis. One change merely relocates a requirement from one section of the LCO to another, and the second change incorporates the recommendations and enhancements as stated in NUREG 1366 and GL 93-05.

Consequently, PSE&G concludes that the change does not involve a significant reduction in any margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Salem Free Public library, 112 West Broadway, Salem, New Jersey 08079

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston and Strawn, 1400 L Street, NW, Washington, DC 20005-3502

NRC Project Director: John F. Stolz

Saxton Nuclear Experimental Corporation, Docket No. 50–146, Saxton Nuclear Facility, Bedford County, Pennsylvania

Date of amendment request: August 1, 1994. This supersedes the request dated June 23, 1993.

Description of amendment request: The proposed amendment would revise the technical specifications to allow characterization activities related to the decommissioning of the Saxton Nuclear Facility and add administrative activities associated with the characterization activities.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed changes do not involve a significant hazards considerations because the changes would not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

The activities associated with characterization of the facility will have a minimum impact on the physical condition of the containment vessel as it relates to the risk of fire and has no effect on the risk of flooding.

2. Create the possibility of a new or different kind of accident from any previously analyzed.

In its present condition, the only accidents applicable to the site are fire, flood, and radiological hazard. The possibility of a new or different type of accident than that previously evaluated in the FSAR will not be created by the implementation of activities permitted by the approval of this amendment request.

3. Involve a significant reduction in a margin of safety.

No margins of safety relevant to the equipment at the facility exist. Activities involved in characterization will not involve a reduction in a margin of safety.

The NRC staff has reviewed the analysis of the licensee and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Saxton Community Library, 911 Church Street, Saxton, Pennsylvania 16678Attorney for the Licensee: Ernest L. Blake, Jr., Esquire, Shaw, Pittman, Potts, and Trowbridge, 2300 N Street, NW, Washington, D.C. 20037

NRC Project Director: Seymour H. Weiss

Southern Nuclear Operating Company, Inc., Docket Nos. 50–348 and 50–364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama

Date of amendments request: October 20, 1994

Description of amendments request: The proposed Technical Specification changes will delete requirements for the chlorine detections systems from Technical Specification 3/4.3.3.6 and its associated bases.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Removal of the control room chlorine detection system does not involve a significant increase in the probability or consequences of an accident previously evaluated because on-site gaseous chlorine will be limited to a maximum per container inventory of 150 pounds located greater than 100 meters from the control room, and manual isolation of the control room is provided. This is in compliance with Regulatory Guide 1.95. Furthermore, offsite chlorine storage and transportation meets the requirements of Regulatory Guides 1.78 and 1.95. Therefore, the probability of occurrence of an accident is not affected.

There are no radiological consequences associated with chlorine release accidents. Therefore, the consequences of an accident previously evaluated are not increased.

2. Removal of the control room chlorine detection system does not create the possibility of a new or different kind of accident from any accident previously evaluated since the chlorine detectors are utilized for detection of accidental chlorine

release and are not accident initiators. Gaseous chlorine has been removed from the plant site, except for a permissible maximum per container inventory of 150 pounds which will be located greater than 100 meters away from the control room. In addition, there is a provision for the manual isolation of the control room. Therefore, on-site chlorine storage meets the requirements of Regulatory Guide 1.95. Furthermore, offsite chlorine storage and transportation meet the requirements of Regulatory Guides 1.78 and 1.95.

3. Removal of the control room chlorine detection system does not involve a significant reduction in the margin of safety related to the protection of control room operators from excessive levels of chlorine since the onsite chlorine storage will be limited to a maximum per container inventory of 150 pounds at the chlorination house, which is located greater than 100 meters from the control room. In addition, manual isolation of the control room is also provided. This meets the requirements of Regulatory Guide 1.95. Therefore, onsite and offsite chlorine storage and transportation meets the requirements of Regulatory Guides 1.78 and 1.95.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Houston-Love Memorial Library, 212 W. Burdeshaw Street, Post Office Box 1369, Dothan, Alabama 36302

Attorney for licensee: M. Stanford Blanton, Esq., Balch and Bingham, Post Office Box 306, 1710 Sixth Avenue North, Birmingham, Alabama 35201

NRC Project Director: William H. Bateman

Tennessee Valley Authority, Docket Nos. 50–259, 50-260 and 50–296, Browns Ferry Nuclear Plant, Units 1, 2 and 3, Limestone County, Alabama

Date of amendment request: October 7, 1994 (TS 351)

Description of amendment request: The proposed amendment clarifies the BFN diesel generator surveillance requirements which were thought to be too ambiguous by both the NRC staff and TVA personnel. In addition, the applicable Bases sections are being reviewed to provide additional background information. TVA is revising Units 1 and 2 TS Surveillance Requirements 4.9.B.3 and Unit 3 TS Surveillance Requirement 4.9.B.2 to more closely reflect the requirements of Improved Standard Technical Specifications (ISTS) for BWR/4s (NUREG–1433), Section 3.8.1, AC Sources—Operating, Condition B for plant operation with an inoperable diesel generator.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change revises the surveillance requirements for plant operation with an inoperable diesel generator. Diesel generator operation is not a precursor to any design basis accident or transient analyzed in the Browns Ferry Updated Final Safety Analysis Report. Therefore, this change does not increase the probability of any previously evaluated accident.

The proposed change will eliminate the requirement for unnecessary diesel generator starts and the incumbent diesel generator wear when a diesel generator is made inoperable for planned maintenance and testing. Thus, the proposed change will result in an increase in the reliability and availability of the diesel generators. Therefore, this change does not increase the consequences of any previously evaluated accident.

2. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change to the surveillance requirements for plant operation with an inoperable diesel generator does not involve a modification to plant equipment. No new failure modes are introduced. There is no effect on the function of any plant system and no new system interactions are introduced by this change.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed amendment does not involve a significant reduction in a margin of safety.

The proposed change will eliminate the requirement for unnecessary diesel generator starts and the incumbent diesel generator wear. Thus, the proposed change will result in an increase in the reliability and availability of the diesel generators. Since the ability of the diesel generators to perform their safety function will not be degraded, the proposed amendment does not involve a reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Athens Public Library, South Street, Athens, Alabama 35611

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11H, Knoxville, Tennessee 37902

NRC Project Director: Frederick J. Hebdon

Tennessee Valley Authority, Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of amendment request: November 2, 1994 (TS 94–17)

Description of amendment request: The proposed change would add Operating License Condition 2.C.(25) to provide temporary extension of the intervals for the surveillance tests specified in the submittal on Unit 1 to coincide with the Cycle 7 refueling outage. The tests would be extended to October 1, 1995, which would result in extension of the specified 18-month, 36-month and 54-month surveillances to 29.5, 48 and 71.5 months, respectively.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

TVA has evaluated the proposed technical specification (TS) change and has determined that it does not represent a significant hazards consideration based on criteria established in 10 CFR 50.92(c). Operation of Sequoyah Nuclear Plant (SQN) in accordance with the proposed amendment will not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change is temporary and allows a one-time extension of specific surveillance requirements (SRs) for Cycle 7 to allow surveillance testing to coincide with the seventh refueling outage. The proposed surveillance interval extension will not cause a significant reduction in system reliability nor affect the ability of the systems to perform their design function. Current monitoring of plant conditions and continuation of the surveillance testing required during normal plant operation will continue to be performed to ensure conformance with TS operability requirements. Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any previously analyzed.

Extending the surveillance interval for the performance of specific testing will not create the posssibility of any new or diffferent kind of accidents. No changes are required to any system configurations, plant equipment, or analyses. Therefore, this change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Involve a significant reduction in a margin of safety.

Surveillance interval extension will not impact any plant safety analyses since the assumptions used will remain unchanged. The safety limits assumed in the accident analyses and the design function of the equipment required to mitigate the consequences of any postulated accidents will not be changed since only the surveillance test interval is being extended. Historical performance generally indicates a high degree of reliability, and surveillance testing performed during normal plant operation will continue to be performed to verify proper performance. Therefore, the plant will be maintained within the analyzed limits, and the proposed extension will not significantly reduce the margin of safety.

The NRC has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Chattanooga-Hamilton County Library, 1101 Broad Street, Chattanooga, Tennessee

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11H, Knoxville, Tennessee 37902

NRC Project Director: Frederick J. Hebdon

Virginia Electric and Power Company, Docket Nos. 50–338 and 50–339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of amendment request: October 25, 1994

Description of amendment request: The proposed change would extend the functional surveillance frequency for the hydrogen recombiners from once per 6 months to once per 18 months. The proposed changes would also delete the surveillance requirement to operate the containment purge blower. Also, minor editorial changes would be made to improve the clarity and consistency between the NA–&2 Technical Specifications (TS).

The NRC has completed a comprehensive examination of surveillance requirements in the TS that require testing at power. The evaluation is documented in NUREG–1366, "Improvements to Technical Specification Surveillance Requirements," dated December 1992. The NRC staff found, that while the majority of testing at power is important, safety can be improved, equipment degradation decreased, and an unnecessary burden on personnel resources eliminated by reducing the amount of testing at power that is required by the TS. Based on the results of the evaluations documented in NUREG–1366, the NRC issued Generic Letter (GL) 93–05, "Line-Item Technical Specifications Improvements to Reduce Surveillance Requirements for Testing During Power Operation," dated September 27, 1993.

The Hydrogen Recombiner System (HRS) removes the hydrogen gasses that accumulate in the containment atmosphere following a design-basis loss-of-coolant accident. Using the guidelines provided by GL 93-05, Item 8.5 and NUREG-1366, the licensee is requesting a change to the functional surveillance testing frequency for the hydrogen recombiners from once per 6 months to once per 18 months. These changes in the surveillance requirements do not affect plant or HRS operations. In addition, several other changes are being requested for clarity and consistency between NA–1&2 TS.

TS Surveillance Requirement 4.6.4.2.a states in part that "... each purge blower operates for 15 minutes." NA–1&2 are equipped with two different types of "purge blowers." One type of purge blowers is an integral part of the HRS. These hydrogen recombiner purge blowers are capable of exhausting containment gasses directly to the atmosphere even with the recombiner incapable of removing hydrogen gas. The second type of purge blowers is the containment purge blowers which exhaust directly from the containment to atmosphere and are not associated with the hydrogen recombiners. Surveillance Requirement 4.6.4.2.a will be modified to state that the purge blowers being referred to in this surveillance requirement are the hydrogen recombiner purge blowers.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Specifically, operation of North Anna Power Station in accordance with the proposed Technical Specifications changes will not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated.

Testing of the Hydrogen Recombiner System once per 18 months will continue to assure that the Hydrogen Recombiner System will be capable of performing its intended functions. The containment purge blowers are not part of the Hydrogen Recombiner System and are not assumed to function during accident conditions. Therefore, these changes to the Hydrogen Recombiner System Technical Specifications do not affect the probability or consequences of any previously analyzed accident.

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed Technical Specification changes do not involve any physical modification of the plant or result in a change in a method of operation. Testing the Hydrogen Recombiner System once per 18 months will continue to assure that the Hydrogen Recombiner System will be capable of performing its intended function. Therefore, a new or different type of accident is not made possible.

(3) Involve a significant reduction in a margin of safety.

The proposed Technical Specification changes do not affect any safety limits or limiting safety system settings. System operating parameters are unaffected. The availability of equipment required to mitigate or assess the consequence of an accident is not reduced. The containment purge blowers are not part of the Hydrogen Recombiner System and are not assumed to function during accident conditions. Testing of the Hydrogen Recombiner System once per 18 months will continue to assure that the Hydrogen Recombiner System will be capable of performing its intended functions. Safety margins are, therefore, not decreased.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: The Alderman Library, Special Collections Department, University of Virginia, Charlottesville, Virginia 22903–2498.

Attorney for licensee: Michael W. Maupin, Esq., Hunton and Williams, Riverfront Plaza, East Tower, 951 E. Byrd Street, Richmond, Virginia 23219.

NRC Project Director: Mohan C. Thadani, Acting

Washington Public Power Supply System, Docket No. 50–397, Nuclear Project No. 2, Benton County, Washington

Date of amendment request: September 2, 1992

Description of amendment request: The proposed amendment would revise the technical specifications to give the correct value for the sodium pentaborate tank low-level alarm.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

The change corrects the Technical Specifications to reflect the correct and more conservative operating capability of the design. In this instance there is no increase in the probability or consequences of an accident previously evaluated because no changes in concentration limits or volume are proposed by this change. The Technical Specifications are being changed to recognize the more prudent operating mode of the SLC [standby liquid control] storage tank in that margin is available, and has always been available, after a low level alarm. The margin allows corrective action to be taken prior to exceeding Technical Specification limits. In summary, a more prudent mode of operating is recognized by this change and the design requirements of volume and concentration are not changed. Hence, the accident analyses remains [sic] unaffected by this change.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

The SLC function and reliability are not affected by this change. No new modes of plant operation are introduced with this change. Hence, no new or different kind of accident is credible.

3. Does the change involve a significant reduction in a margin of safety?

No change to the required volume and concentrations are being proposed by this [modification]. Neither the original design or accident analysis is affected by this change. A more prudent mode of operation, that currently exists, is recognized by this proposal. Therefore, there is no impact to a margin of safety with this change.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Richland Public Library, 955 Northgate Street, Richland, Washington 99352

Attorney for licensee: M. H. Philips, Jr., Esq., Winston & Strawn, 1400 L Street, NW., Washington, D.C. 20005-3502

NRC Project Director: Theodore R. Quay Wolf Creek Nuclear Operating Corporation, Docket No. 50–482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: October 21, 1994 and supplement dated October 27, 1994

Description of amendment request: This amendment request revises Technical Specification Surveillance Requirements 4.7.1.2.1.c.2 (operability testing for the turbine-driven auxiliary feedwater (AFW) pump automatic start feature) and 4.3.2.2 (engineered safety feature actuation system instrumentation response time testing for the turbine-driven AFW pump) to correct an inconsistency caused by system-limitations to supply steam to the turbine-driven AFW pump prior to entry into Mode 3. These specifications are being revised to indicate that the provisions of Technical Specification 4.0.4 are not applicable for entry into Mode 3.

In addition, Technical Specification Surveillance Requirement 4.7.1.2.1.c is being revised to delete the requirement to be performed during shutdown.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

WCNOC [Wolf Creek Nuclear Operating Corporation] is proposing to modify Surveillance Requirements 4.3.2.2 and 4.7.1.2.1.c.2 by adding an exemption for [from] the provisions of Technical Specification 4.0.4 and deleting the shutdown requirement. Entry into Mode 3 would allow for appropriate test conditions (e.g., adequate steam pressure available) to complete the operability testing of the turbine-driven AFW pump. The acceptance criteria such as response time, or test frequency, are not revised. Therefore, the surveillance will continue to verify the operability of the turbine-driven AFW pump. Additionally, the proposed changes are consistent with the new improved Standard Technical Specifications for Westinghouse plants (NUREG-1431)

Considering the above, the proposed changes to Surveillance Requirements 4.3.2.2 and 4.7.1.2.1.c.2, of the WCGS [Wolf Creek Generating Station] Technical Specifications, do not involve a significant increase in the probability or consequences of an accident previously analyzed.

2. The proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

The proposed changes do not make any physical or operational changes to existing plant structures, systems, or components. The proposed changes do not introduce any new failure modes. They simply allow tests to be performed at appropriate conditions rather than during shutdown.

Additionally, the proposed changes do not modify the acceptance criteria for the tests. The purpose of the tests is to ensure that the turbine-driven AFW pump can perform its intended function.

Thus, the proposed changes do not create the possibility of a new or different kind of accident from any previously analyzed.

3. The proposed changes do not involve a significant reduction in the margin of safety.

The proposed changes do not have any adverse impact on the Updated Safety Analysis Report accident analyses. The applicable acceptance criteria for the turbine-driven AFW pump will not be modified by these proposed changes. The proposed changes will permit the tests to be conducted under the proper conditions, so that the ability of the turbine-driven AFW pump to perform its intended safety function can be confirmed.

Based on the above discussions it has been determined that the requested technical specification revision does not involve a significant increase in the probability or consequences of an accident or other adverse condition; or involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room locations: Emporia State University, William Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas 66621

Attorney for licensee: Jay Silberg, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037

NRC Project Director: Theodore R. Quay

Previously Published Notices of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed no Significant Hazards Consideration Determination, and Opportunity for a Hearing

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

Philadelphia Electric Company, Public Service Electric and Gas Company, Delmarva Power and Light Company, and Atlantic City Electric Company, Docket Nos. 50–277 and 50–278, Peach Bottom Atomic Power Station, Unit Nos. 2 and 3, York County, Pennsylvania

Date of amendment request: October 25, 1994

Brief description of amendment request: The proposed amendment would clarify the minimum reactor steam pressure required for Surveillance Requirement (SR) 4.5.C.1(e). The revised SR will require the licensee to verify that the High Pressure Coolant Injection Pump, with reactor pressure less than or equal to 175 psig, develop a flow rate of greater than or equal to 5000 gpm against a system head corresponding to reactor pressure. The current SR specifies that the test be performed at 150 psig but does not provide a range of acceptable pressures.

Date of publication of individual notice in Federal Register: NOV. 7, 1994 (59 FR 55498)

Expiration date of individual notice: December 7, 1994

Local Public Document Room location: Government Publications Section, State Library of Pennsylvania, (REGIONAL DEPOSITORY) Education Building, Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, Pennsylvania 17105.

Notice of Issuance of Amendments to Facility Operating Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document rooms for the particular facilities involved.

Arizona Public Service Company, et al., Docket Nos. STN 50-528, STN 50-529, and STN 50-530, Palo Verde Nuclear Generating Station, Units 1, 2, and 3, Maricopa County, Arizona

Date of application for amendments: June 17, 1994, supplemented by letter dated September 21, 1994.

Brief description of amendments: The amendments allow removal of five tables of component lists from the Palo Verde Technical Specifications (TS) in accordance with NRC Generic Letter (GL) 91–08, "Removal of Component Lists from Technical Specifications." The affected tables are Table 3.3–9B, Table 3.3–9C, Table 3.6–1, Table 3.8–2, and Table 3.8–3. These five removed tables will be incorporated into a new document, which will be administratively controlled according to the change control provisions of the TS.

Date of issuance: October 31, 1994

Effective date: October 31, 1994, to be implemented no later than 45 days from the date of issuance.

Amendment Nos.: 85, 73, and 57

Facility Operating License Nos. NPF–41, NPF–51, and NPF–74: The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 20, 1994 (59 FR 37061) The supplemental letter provided certain revised TS pages for clarification purposes and did not change the original no significant hazards determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 31, 1994. No significant hazards consideration comments received: No.

Local Public Document Room location: Phoenix Public Library, 12 East McDowell Road, Phoenix, Arizona 85004

Arizona Public Service Company, et al., Docket Nos. STN 50–528, STN 50–529, and STN 50–530, Palo Verde Nuclear Generating Station, Units 1, 2, and 3, Maricopa County, Arizona

Date of application for amendments: January 4, 1994

Brief description of amendments: These amendments revise Technical Specification 3.2.3, "Azimuthal Power Tilt," to change the azimuthal power tilt limit from less than or equal to 10 percent to less than or equal to 3 percent when the core operating limit supervisory system is out of service. The associated TS Bases are similarly changed.

Date of issuance: November 3, 1994

Effective date: November 3, 1994, to be fully implemented no later than 45 days from the date of issuance

Amendment Nos.: 86, 74, and 58

Facility Operating License Nos. NPF–41, NPF–51, and NPF–74: The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** April 28, 1994 (59 FR 22001) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 3, 1994.No significant hazards consideration comments received: No.

Local Public Document Room location: Phoenix Public Library, 12 East McDowell Road, Phoenix, Arizona 85004

Baltimore Gas and Electric Company, Docket No. 50–318, Calvert Cliffs Nuclear Power Plant, Unit No. 2, Calvert County, Maryland

Date of application for amendment: May 27, 1993

Brief description of amendment: The amendment revises the heatup and cooldown curves and the low-temperature overpressure protection (LTOP) controls. The changes to the LTOP controls support proposed modifications to allow a variable-setpoint (VLTOP) protection system. The VLTOP system will increase the allowable operating pressure band in the LTOP region and increase the flexibility in the use of the reactor coolant pumps.

Date of issuance: November 1, 1994

Effective date: As of the date of issuance to be implemented within 30 days.

Amendment No.: 178

Facility Operating License No. DPR–69: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 29, 1993 (59 FR 37064) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 1, 1994. No significant hazards consideration comments received: No

Local Public Document Room location: Calvert County Library, Prince Frederick, Maryland 20678.

Carolina Power & Light Company, Docket No. 50–261, H. B. Robinson SteamElectric Plant, Unit No. 2, Darlington County, South Carolina

Date of application for amendment: November 4, 1993, as supplemented April 27, 1994, and October 10, 1994.

Brief description of amendment: The proposed amendment revises Technical Specification 6.13.1 to provide use of alarming dosimeters in high radiation areas. This change includes newly revised 10 CFR Part 20 requirement references and is consistent with NUREG-1413, Standard Technical Specifications—Westinghouse Plants, Specification 5.11.1.

Date of issuance: November 4, 1994

Effective date: November 4, 1994

Amendment No.: 152

Facility Operating License No. DPR–23. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** February 2, 1994 (59 FR 4935) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 4, 1994. No significant hazards consideration comments received: No

Local Public Document Room location: Hartsville Memorial Library, 147 West College, Hartsville, South Carolina 29550

Carolina Power & Light Company, et al., Docket No. 50-400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

Date of application for amendment: September 28, 1993, as amended April 5, 1994.

Brief description of amendment: The amendment revises Technical Specification 3/4.8.1, "AC Sources—Operating", and associated Bases to be consistent with the new "Standard Technical Specifications for Westinghouse Plants", NUREG–1431, Revision 0.

Date of issuance: November 4, 1994

Effective date: November 4, 1994

Amendment No. 51

Facility Operating License No. NPF–63. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** October 27, 1993 (58 FR 57845) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 4, 1994. No significant hazards consideration comments received: No

Local Public Document Room location: Cameron Village Regional Library, 1930 Clark Avenue, Raleigh, North Carolina 27605.

Commonwealth Edison Company, Iowa-Illinois Gas and Electric Company, Docket Nos. 50-237 and 50-249, Dresden Nuclear Power Station, Units 2 and 3, Grundy County, Illinois; Docket Nos. 50–254 and 50–265, Quad Cities Nuclear Power Station, Units 1 and 2, Rock Island County, Illinois; Docket Nos. 50–295 and 50–304, Zion Nuclear Power Station, Units 1 and 2, Lake County, Illinois

Date of application for amendments: July 8, 1994

Brief description of amendments: The amendment revises the operating licenses by adding a license condition that would allow the commitments made in response to NUREG–0737, "Clarification of TMI Action Plan Requirements," to be controlled pursuant to the requirements of 10 CFR 50.59.

Date of issuance: November 3, 1994

Effective date: November 3, 1994

Amendment Nos.: for Dresden, Amendment Nos. 129 and 123; for Quad Cities, Amendment Nos. 150 and 146; and for Zion, Amendment Nos. 158 and 146.

Facility Operating License Nos. DPR–19, DPR–25, DPR–29, DPR–30, DPR–39, and DPR–48. The amendments revised the operating licenses.

Date of initial notice in **Federal Register:** August 31, 1994 (59 FR 45021) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 3, 1994. No significant hazards consideration comments received: No

Local Public Document Room locations: for Dresden, the Morris Public Library, 604 Liberty Street, Morris, Illinois 60450; for Quad Cities, the Dixon Public Library, 221 Hennepin Avenue, Dixon, Illinois 61021; and for Zion, the Waukegan Public Library, 128 N. County Street, Waukegan, Illinois 60085.

Detroit Edison Company, Docket No. 50–16, Enrico Fermi Power Plant, Unit 1, Monroe County, Michigan

Date of application for amendment: December 9, 1993 (Reference NRC–93–0143).

Brief description of amendment: This amendment modified the Technical Specifications (TS) incorporated in Possession-Only License No. DPR-9 as Appendix A by modifying the Protected Area definition and Waste Disposal Surveillances to provide the appropriate 10 CFR Part 20 references in conformance with a revision of 10 CFR Part 20 (56 FR 23360).

Date of issuance: November 3, 1994.

Effective date: This license amendment is effective as of the date of its issuance and must be fully implemented no later than 30 days from the date of issuance.

Amendment No.: 10.Possession-Only License No. DPR-9: The amendment revised the TS.

Date of initial notice in **Federal Register:** July 20, 1994 (59 FR 37070) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 3, 1994.No significant hazards consideration comments received: No.

Local Public Document Room location: Monroe County Library System, 3700 South Custer Road, Monroe, Michigan 48161.

Duke Power Company, Docket Nos. 50-369 and 50-370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of application for amendments: November 21, 1991.

Brief description of amendments: The amendments were submitted as a result of NRC recommendations pertaining to Generic Letter 90–06 for the power-operated relief valves and block valves and low-temperature overpressure protection systems.

Date of issuance: October 27, 1994

Effective date: October 27, 1994

Amendment Nos.: 150 and 132

Facility Operating License Nos. NPF–9 and NPF–17: Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** November 10, 1993 (58 FR 59748) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated Ocotber 27, 1994.No significant hazards consideration comments received: No.

Local Public Document Room location: Atkins Library, University of North Carolina, Charlotte (UNCC Station), North Carolina 28223

Duke Power Company, Docket Nos. 50–269, 50–270, and 50–287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina

Date of application of amendments: December 8, 1993, as supplemented April 20, September 8, 1994, and October 25, 1994.

Brief description of amendments: The amendments revise Technical Specification 3.4 to address the need to bypass automatic initiation of the Emergency Feedwater system with the main feedwater pump discharge pressure is below actuation setpoint during startup and shutdown in order to prevent inadvertent actuation. The amendments also deleted operability requirements for the Emergency Condenser Cooling Water (ECCW) system.

Date of Issuance: October 31, 1994
Effective date: To be implemented within 30 days from the date of issuance.
Amendment Nos.: 207, 207, and 204
Facility Operating License Nos. DPR–38, DPR–47, and DPR–55: The amendments revised the Technical Specifications.
Date of initial notice in **Federal Register:** August 3, 1994 (59 FR 39584) The April 20, September 8, and October 25, 1994 supplements provided additional information that did not change the scope of the December 8, 1994, application and the initial proposed no significant hazards consideration determination.The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 31, 1994. No significant hazards consideration comments received: No
Local Public Document Room location: Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina 29691

Entergy Operations, Inc., Docket No. 50–382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: February 5, 1993, as supplemented by letter dated August 1, 1994.
Brief description of amendment: The amendment revised the Technical Specifications to incorporate a technical review and control process to supplement the onsite technical review and approval of new procedures and changes thereto affecting nuclear safety.
Date of issuance: November 4, 1994Effective date: November 4, 1994
Amendment No.: 100
Facility Operating License No. NPF–38. Amendment revised the Technical Specifications.
Date of initial notice in **Federal Register:** August 31, 1994 (59 FR 45022) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 4, 1994.No significant hazards consideration comments received: No.
Local Public Document Room location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122.

Florida Power and Light Company, et al., Docket No. 50–389, St. Lucie Plant, Unit No. 2, St. Lucie County, Florida

Date of application for amendment: May 23, 1994
Brief description of amendment: This amendment revises Technical Specifications Section 3/4.7.1.1, Turbine Cycle, Safety Valves, to delete a specific reference to the 1994 edition of the ASME Code and refer to testing in accordance with Technical Specification 4.0.5, the In-Service Inspection and In-Service Testing Specification.
Date of Issuance: November 1, 1994
Effective Date: November 1, 1994
Amendment No.: 68
Facility Operating License No. NPF–16: Amendment revised the Technical Specifications.
Date of initial notice in **Federal Register:** July 6, 1994 (59 FR 34664) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 1, 1994No significant hazards consideration comments received: No.
Local Public Document Room location: Indian River Junior College Library, 3209 Virginia Avenue, Fort Pierce, Florida 34954-9003

IES Utilities Inc., Docket No. 50-331, Duane Arnold Energy Center, Linn County, Iowa

Date of application for amendment: June 30, 1994
Brief description of amendment: The proposed amendment would clarify the requirement for the audit of conformance to Technical Specifications, delete the requirement for Safety Committee oversight of the Emergency Plan and Security Plan and allow designation by the Plant Superintendent signature authority for procedure approval.
Date of issuance: November 2, 1994
Effective date: Date of issuance and to be implemented within 60 days
Amendment No.: 202
Facility Operating License No. DPR-49. Amendment revised the Technical Specifications.
Date of initial notice in **Federal Register:** August 3, 1994 (59 FR 39591) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 2, 1994No significant hazards consideration comments received: No.
Local Public Document Room location: Cedar Rapids Public Library, 500 First Street, S. E., Cedar Rapids, Iowa 52401.

Illinois Power Company and Soyland Power Cooperative, Inc., Docket No. 50–461, Clinton Power Station, Unit No. 1, DeWitt County, Illinois

Date of application for amendment: August 12, 1994
Brief description of amendment: The amendment modifies Clinton Power Station Technical Specification 3/4.6.2.2, "Drywell Bypass Leakage," to allow drywell bypass leakage rate tests to be performed at intervals as long as five years based on the demonstrated performance of the drywell structure.
Date of issuance: November 3, 1994
Effective date: November 3, 1994
Amendment No.: 94
Facility Operating License No. NPF–62. The amendment revised the Technical Specifications.
Date of initial notice in **Federal Register:** September 28, 1994 (59 FR 49428) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 3, 1994. No significant hazards consideration comments received: No
Local Public Document Room location: The Vespasian Warner Public Library, 120 West Johnson Street, Clinton, Illinois 61727.

Indiana Michigan Power Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of application for amendments: November 12, 1993
Brief description of amendments: The amendments revise the Technical Specifications for the accumulators to allow extended action time for improper boron concentration, to provide a consistent action statement for both units, and to modify the surveillances on the boron concentration and the isolation valve.
Date of issuance: November 8, 1994
Effective date: November 8, 1994
Amendment Nos.: 184 and 169
Facility Operating License Nos. DPR–58 and DPR–74. Amendments revised the Technical Specifications.
Date of initial notice in **Federal Register:** December 22, 1993 (58 FR 67848). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 8, 1994.No significant hazards consideration comments received: No.
Local Public Document Room location: Maud Preston Palenske Memorial Library, 500 Market Street, St. Joseph, Michigan 49085.

Indiana Michigan Power Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of application for amendments: December 22, 1993
Brief description of amendments: The amendments revise the action statement in the Technical Specifications for Steam Generator Stop Valves to be more consistent with NUREG–1431, Standard Technical Specifications Westinghouse

Plants. The proposed changes allow both greater time for compensatory action as well as operation in Modes 2 and 3 with valves inoperable but closed. A Unit 2 action requirement is also revised.

Date of issuance: November 8, 1994
Effective date: November 8, 1994
Amendment Nos.: 185 and 170
Facility Operating License Nos. DPR-58 and DPR-74. Amendments revised the Technical Specifications.
Date of initial notice in **Federal Register:** February 2, 1994 (59 FR 4939) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 8, 1994. No significant hazards consideration comments received: No.
Local Public Document Room location: Maud Preston Palenske Memorial Library, 500 Market Street, St. Joseph, MI 49085.

Niagara Mohawk Power Corporation, Docket Nos. 50–220, and 50–410, Nine Mile Point Nuclear Station, Unit Nos. 1 and 2, Oswego County, New York

Date of application for amendments: June 9, 1994
Brief description of amendments: The amendments modify paragraph 2.D(4) of *Facility Operating License No.* DPR–63 and paragraph 2.E of *Facility Operating License No.* NPF–69 to require compliance with the amended Physical Security Plan. The changes involve the number of armed security force members that comprise the response force for each shift at the site.
Date of issuance: October 31, 1994
Effective date: As of the date of issuance to be implemented within 30 days.
Amendment Nos.: Unit 1—150—Unit 2—58
Facility Operating License Nos. DPR–63 and NPF–69: Amendments revise the Facility Operating Licenses.
Date of initial notice in **Federal Register:** September 28, 1994 (59 FR 49432) The Commission's related evaluation of the amendments is contained in a Safeguards Evaluation Report dated October 31, 1994. No significant hazards consideration comments received: No
Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Northeast Nuclear Energy Company, et al., Docket No. 50–336, Millstone Nuclear Power Station, Unit No. 2, New London County, Connecticut

Date of application for amendment: September 26, 1994
Brief description of amendment: The amendment revises the Technical Specifications (TS) by adding a footnote to Surveillance Requirement 4.6.1.2.d that defers the performance of Type B and C Containment leak rate tests to the end of the twelfth refueling outage.
Date of issuance: October 31, 1994
Effective date: October 31, 1994
Amendment No.: 181
Facility Operating License No. DPR–65. Amendment revised the Technical Specifications. Public comments requested as to proposed no significant hazards consideration: Yes (59 FR 52005, October 13, 1994) That notice provided an opportunity to submit comments on the Commission's proposed no significant hazards consideration determination. No comments have been received. The notice also provided for an opportunity to request a hearing by November 14, 1994, but indicated that if the Commission makes a final no significant hazards consideration determination any such hearing would take place after issuance of the amendment. The Commission's related evaluation of the amendment, finding of exigent circumstances, and final determination of no significant hazards consideration are contained in a Safety Evaluation dated October 31, 1994.
Local Public Document Room location: Learning Resource Center, Three Rivers Community-Technical College, Thames Valley Campus, 574 New London Turnpike, Norwich, CT 06360.
Attorney for licensee: Ms. L. M. Cuoco, Senior Nuclear Counsel, Northeast Utilities Service Company, Post Office Box 270, Hartford, CT 06141-0270.

Northeast Nuclear Energy Company, et al., Docket No. 50-336, Millstone Nuclear Power Station, Unit No. 2, New London County, Connecticut

Date of application for amendment: September 1, 1994
Brief description of amendment: The amendment revises the Technical Specifications concerning the Reactor Coolant System Volume.Date of issuance: November 8, 1994
Effective date: As of the date of issuance to be implemented within 30 days.
Amendment No.: 182
Facility Operating License No. DPR–65. Amendment revised the Technical Specifications.
Date of initial notice in **Federal Register:** September 28, 1994 (59 FR 49432). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 8, 1994. No significant hazards consideration comments received: No.
Local Public Document Room location: Learning Resource Center, Three Rivers Community-Technical College, Thames Valley Campus, 574 New London Turnpike, Norwich, CT 06360.

Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of application for amendments: February 16, 1994 (Reference LAR 94–04)
Description of amendment request: The proposed amendments revise the combined Technical Specifications (TS) for the Diablo Canyon Power Plant, Unit Nos. 1 and 2. Specifically, TS 4.2.2, "Heat Flux Hot Channel Factor—$F_Q(z)$," and 6.9.1.8, "Core Operating Limits Report," are revised as follows: (1) The 2-percent $F_Q(z)$ penalty listed in TS 4.2.2.2.e.1) would be deleted and the statement revised to indicate the use of an appropriate factor to be specified in the Core Operating Limits Report (COLR). (2) TS 6.9.1.8.b.1 would be changed to reference Revision 1 of WCAP 10216–P–A, "Relaxation of Constant Axial Offset Control $F_Q(z)$ Surveillance Technical Specification," dated February 1994.
Date of issuance: October 31, 1994
Effective date: 60 days from date of issuance.
Amendment Nos.: 96 and 95
Facility Operating License Nos. NPF–10 and NPF–15: The amendments revised the Technical Specifications.
Date of initial notice in **Federal Register:** April 13, 1994 (59 FR 17603) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 31, 1994. No significant hazards consideration comments received: No.
Local Public Document Room location: California Polytechnic State University, Robert E. Kennedy Library, Government Documents and Maps Department, San Luis Obispo, California 93407No significant hazards consideration comments received: No.
Facility Operating License Nos. NPF–10 and NPF–15: The amendments revised the Technical Specifications.
Date of initial notice in **Federal Register:** April 13, 1994 (59 FR 17603) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 31, 1994. No significant hazards consideration comments received: No.

Local Public Document Room location: California Polytechnic State University, Robert E. Kennedy Library, Government Documents and Maps Department, San Luis Obispo, California 93407

PECO Energy Company, Docket No. 50–171, Peach Bottom Atomic Power Station, Unit 1, Peach Bottom, Pennsylvania.

Date of application for amendment: May 9, 1994.

Brief description of amendment: This amendment modified Possession-Only License No. DPR–12 and the Technical Specifications (TS) incorporated as Appendix A by changing the name of Philadelphia Electric Company to PECO Energy Company, by providing the appropriate 10 CFR Part 20 references, and by reducing the required frequency for performing periodic inspections in the containment vessel below ground level for water accumulation.

Date of issuance: November 3, 1994.

Effective date: This license amendment is effective as of the date of its issuance and must be fully implemented no later than 30 days from the date of issuance.

Amendment No.: 8.Possession-Only License No. DPR–12: The amendment revised Possession-Only License No. DPR–12 and the TS.

Date of initial notice in **Federal Register:** August 31, 1994 (59 FR 45030) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 3, 1994.No significant hazards consideration comments received: No.

Local Public Document Room location: Government Publications Section, State Library of Pennsylvania, (REGIONAL DEPOSITORY) Education Building, Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, Pennsylvania 17105.

Philadelphia Electric Company, Docket Nos. 50–352 and 50–353, Limerick Generating Station, Units 1 and 2, Montgomery County, Pennsylvania

Date of application for amendments: September 16, 1994

Brief description of amendments: These amendments extend the snubber functional testing interval from 18 months (+/- 25%) to 24 months (+/- 25%) (plus or minus was published as [greater than or equal to] in the initial **Federal Register** notice), and increase the sample plan size from 10 percent to 13.3 percent. The combination of these two changes will ensure that the entire population of snubbers will be tested in a 15-year period.

Date of issuance: November 2, 1994

Effective date: November 2, 1994Amendment Nos. 81 and 42

Facility Operating License Nos. NPF-39 and NPF-85. The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 30, 1994 (59 FR 50019) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 2, 1994.No significant hazards consideration comments received: No

Local Public Document Room location: Pottstown Public Library, 500 High Street, Pottstown, Pennsylvania 19464.

Power Authority of the State of New York, Docket No. 50-286, Indian Point Nuclear Generating Unit No. 3, Westchester County, New York

Date of application for amendment: September 16, 1992, supplemented June 27, 1994, and September 26, 1994

Brief description of amendment: The amendment revised Technical Specifications Section 4.6.B (Emergency Power System Periodic Tests—Station Batteries) to incorporate changes which allow battery testing surveillance interval extensions to accommodate operation on a 24-month fuel cycle. These changes followed the guidance provided in Generic Letter 91–04, "Changes in Technical Specification Surveillance Intervals to Accommodate a 24–Month Fuel Cycle," as applicable.

Date of issuance: November 2, 1994

Effective date: November 2, 1994

Amendment No.: 155

Facility Operating License No. DPR–64: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** October 28, 1992 (57 FR 48825) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 2, 1994.No significant hazards consideration comments received: No

Local Public Document Room location: White Plains Public Library, 100 Martine Avenue, White Plains, New York 10610.

Power Authority of the State of New York, Docket No. 50–333, James A. FitzPatrick Nuclear Power Plant, Oswego County, New York

Date of application for amendment: July 21, 1994, as supplemented September 26, 1994.

Brief description of amendment: The amendment relocates fire protection requirements from the Technical Specifications to the plant fire protection program in accordance with the guidance provided in Generic Letter (GL) 86–10, "Implementation of Fire Protection Requirements," and GL 88–12, "Removal of Fire Protection Requirements from the Technical Specifications." The amendment also modifies the Facility Operating License to incorporate the standard fire protection license condition provided in GL 86–10.

Date of issuance: November 3, 1994

Effective date: As of the date of issuance to be implemented within 30 days.

Amendment No.: 218

Facility Operating License No. DPR–59: Amendment revised the Technical Specifications and License.

Date of initial notice in **Federal Register:** August 17, 1994 (59 FR 42345) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 3, 1994.No significant hazards consideration comments received: No

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Public Service Electric & Gas Company, Docket Nos. 50–272 and 50–311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey Date of application for amendments: August 19, 1994, as supplemented October 4, 1994

Brief description of amendments: The amendments reduce the minimum setpoints and allowable values for the steam generator low and low-low level reactor protection system signals.

Date of issuance: November 4, 1994

Effective date: November 4, 1994

Amendment Nos. 159 and 140

Facility Operating License Nos. DPR–70 and DPR–75. The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 14, 1994 (59 FR 47180) The supplemental letter provides additional information but does not change the initial proposed no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 4, 1994. No significant hazards consideration comments received: No

Local Public Document Room location: Salem Free Public Library, 112 West Broadway, Salem, New Jersey 08079

Public Service Electric & Gas Company, Docket Nos. 50–272 and 50–311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of application for amendments: June 13, 1994

Brief description of amendments: These amendments add a new section 3.0.6 to the technical specifications and the associated Bases, that permits an out-of-service component to be returned to service under administrative controls for the purpose of determining operability, and make an editorial correction.

Date of issuance: November 8, 1994

Effective date: November 8, 1994

Amendment Nos. 160 and 141

Facility Operating License Nos. DPR–70 and DPR–75. The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 3, 1994 (59 FR 39590) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 8, 1994.No significant hazards consideration comments received: No

Local Public Document Room location: Salem Free Public Library, 112 West Broadway, Salem, New Jersey 08079

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Date of application for amendment: December 17, 1993

Brief description of amendment: The change revises TS 3/4.3.3.6, Accident Monitoring Instrumentation, and its associated bases; relocates TS 3/4.6.5.1, Hydrogen Monitors, and TS 3/4.3.3.1, Tables 3.3–6 and 4.3–3, Item 1.c, Reactor Building Area High Range Radiation Monitors, into the Accident Monitoring TS.

Date of issuance: November 7, 1994

Effective date: November 7, 1994

Amendment No.: 118

Facility Operating License No. NPF–12. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** February 16, 1994 (59 FR 7699) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 7, 1994.No significant hazards consideration comments received: No

Local Public Document Room location: Fairfield County Library, Garden and Washington Streets, Winnsboro, South Carolina 29180.

Tennessee Valley Authority, Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of application for amendments: May 16, 1994 (TS 94–03)

Brief description of amendments: The amendments remove the response time limits for the reactor trip and engineered safety feature functions from the technical specifications in accordance with Generic Letter 93–08.

Date of issuance: November 9, 1994

Effective date: November 9, 1994

Amendment Nos.: 190 and 182

Facility Operating License Nos. DPR–77 and DPR–79: Amendments revise the technical specifications.

Date of initial notice in **Federal Register:** June 22, 1994 (59 FR 32236) The Commission's related evaluation of the amendments are contained in a Safety Evaluation dated November 9, 1994No significant hazards consideration comments received: None

Local Public Document Room location: Chattanooga-Hamilton County Library, 1101 Broad Street, Chattanooga, Tennessee 37402

TU Electric Company, Docket Nos. 50–445 and 50–446, Comanche Peak Steam Electric Station, Unit Nos. 1 and 2, Somervell County, Texas

Date of amendment request: September 19, 1994

Brief description of amendments: The amendments allow a one-time six-month extension for certain emergency diesel generator technical specification surveillance requirements and other related surveillance requirements. The one-time extension from 18 to 24 months for the affected surveillance requirements is applicable only to Unit 2, Train A, until completion of the second refueling outage for Unit 2.

Date of issuance: November 2, 1994

Effective date: Effective as of its date of issuance, to be implemented within 30 days.

Amendment Nos.: Unit 1—Amendment No. 31; Unit 2—Amendment No. 17

Facility Operating License Nos. NPF-87 and NPF-89. The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 30, 1994 (59 FR 50024) The October 20, 1994, submittal provided additional clarifying information and did not change the initial no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 2, 1994. No significant hazards consideration comments received: No.

Local Public Document Room location: University of Texas at Arlington Library, Government Publications/Maps, 702 College, P.O. Box 19497, Arlington, Texas 76019.

TU Electric Company, Docket Nos. 50–445 and 50–446, Comanche Peak Steam Electric Station, Unit Nos. 1 and 2, Somervell County, Texas

Date of amendment request: September 19, 1994

Brief description of amendments: The amendments revise the technical specifications by eliminating the requirement that the 18-month surveillance requirements (SRs) for the emergency core cooling, containment spray, spray additive, containment isolation valves, auxiliary feedwater and component cooling water systems be performed "during shutdown" or "during REFUELING MODE or COLD SHUTDOWN." The SRs are still required to be performed on an 18-month surveillance interval, but may be performed in any mode in which it is technically and operationally acceptable to perform the testing.

Date of issuance: November 2, 1994

Effective date: Within 30 days of its date of issuance

Amendment Nos.: Unit 1—Amendment No. 32; Unit 2—Amendment No. 18

Facility Operating License Nos. NPF–87 and NPF–89. The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 30, 1994 (59 FR 50022) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 2, 1994.No significant hazards consideration comments received: No.

Local Public Document Room location: University of Texas at Arlington Library, Government Publications/Maps, 702 College, P.O. Box 19497, Arlington, Texas 76019.

Wisconsin Public Service Corporation, Docket No. 50–305, Kewaunee NuclearPower Plant, Kewaunee County, Wisconsin

Date of application for amendment: March 31, 1994

Brief description of amendment: The amendment revises the Kewaunee Nuclear Power Plant Technical Specifications (TS) by incorporating operability and surveillance requirements for the recently installed Auxiliary Feedwater Pump Low Discharge Pressure Trip instrumentation. Surveillance requirements were added to Table TS 4.1–1, "Minimum Frequencies for

Checks, Calibrations and Test of Instrument Channels." TS 3.4, "Steam and Power Conversions System," has been revised to explicitly link operability of the associated Auxiliary Feedwater Pump Low Discharge Pressure Trip channel to operability of the associated auxiliary feedwater pump. In addition, minor format inconsistencies in TS 3.4.b.1.A and 3.4.b.1.B were corrected.

Date of issuance: November 1, 1994

Effective date: Date of issuance, to be implemented within 30 days

Amendment No.: 112

Facility Operating License No. DPR–43. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 6, 1994 (59 FR 34671) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 1, 1994. No significant hazards consideration comments received: No.

Local Public Document Room location: University of Wisconsin Library Learning Center, 2420 Nicolet Drive, Green Bay, Wisconsin 54301.

Dated at Rockville, Maryland, this 16th day of November 1994.

For the Nuclear Regulatory Commission.

Steven A. Varga,

Director, Division of Reactor Projects—I/II Office of Nuclear Reactor Regulation

[Doc. 94-28758 Filed 11-22-94; 8:45 am]

BILLING CODE 7590-01-F

[IA–94–032]

Michael J. Berna; Order Prohibiting Involvement in NRC Licensed Activities (Effective Immediately)

I

Amoco Oil Company (Amoco or Licensee) was the holder of Byproduct Material License No. 13–00155–10 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 34. The license authorized the use of byproduct material (iridium-192 and cobalt-60) for industrial radiography in devices approved by the NRC or an Agreement State. The facility where licensed materials were authorized for use and storage was located at 2815 Indianapolis Boulevard, Whiting, Indiana. The use of licensed material was authorized at temporary job sites anywhere in the United States where the United States Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material. The License was originally issued on February 4, 1958, and was terminated on October 19, 1993.

Mr. Michael J. Berna performed duties as the Licensee's Radiation Safety Officer (RSO) from March 1990 until he was relieved of those duties on October 16, 1992.

II

On July 27, 1992, the NRC Region III office received information that Mr. Berna had not conducted field audits of radiographers and radiographer's assistants as required by license conditions and that Mr. Berna fabricated reports for the audits that he did not perform by documenting that the audits had been performed. The NRC conducted an inspection at the Licensee's Whiting, Indiana, refinery from September 15 to October 9, 1992. The NRC Office of Investigations (OI) subsequently conducted an investigation. The Licensee conducted an investigation contemporaneously with the NRC inspection and investigation. Deliberate violations of NRC requirements were identified as a result of the NRC inspection and the investigation.

Condition 18.A of License No. 13–00155–10 incorporates the statements, representations, and procedures contained in the license application dated March 28, 1990. Item 10.3 of that application required, in part, that practicing radiographers and radiographer's assistants are to be audited at intervals not to exceed 3 months to meet the requirements of 10 CFR Part 34 and the Licensee's Operating and Emergency Procedures, and that the audits should be unannounced insofar as possible. Item 10.5 of that application required, in part, that certain records be generated and maintained, including a record of quarterly audits of radiographers and radiographer's assistants.

Mr. Berna admitted to the NRC in a sworn, transcribed interview on October 7, 1992, that he knowingly failed to perform the required audits and that he deliberately falsified records to show that audits had been performed on at least ten occasions (February 6, 10, 12, and 29, April 11, 22, 24, and 29, May 12, and September 1, 1992).

In addition, during the September 15, 1992, inspection the NRC inspector asked Mr. Berna if the field audits of radiographers and radiographer's assistants were unannounced. Mr. Berna told the NRC inspector that he did not give any advance notification to radiography personnel. However, the testimony of eight radiographers or radiographer's assistants indicated that Mr. Berna always informed them when he would be performing an audit.

Testimony provided by an Assistant Radiation Safety Officer (ARSO) on November 5, 1992, indicated that at the request of Mr. Berna on or about September 15, 1992, the ARSO falsified at least two records of audits of radiographers and radiographer's assistants for May 1992. Also, testimony provided to OI by another ARSO on December 17, 1992, indicated that at the request of Mr. Berna during August 1991, this ARSO falsified at least two records of audits of radiographers and radiographer's assistants.

These actions are contrary to the audit requirements and the records generation and maintenance requirements of the License, and a violation of 10 CFR 30.9(a), "Completeness and Accuracy of Information," and 10 CFR 30.19(a) (1) and (2), "Deliberate Misconduct," of the Commission's regulations.

The Licensee conducted an internal investigation and based on the results of its investigation the Licensee suspended Mr. Berna's employment for one month without pay. On December 1, 1992, a Confirmatory Order Modifying License (Effective Immediately) was issued to the Licensee, which confirmed, among other things, that the Licensee would prohibit Mr. Berna from participating in any NRC licensed activities, including the position of RSO.

III

Based on the above, it appears that Mr. Berna engaged in deliberate misconduct from August 1991 through approximately September 15, 1992, by failing to conduct field audits of radiographers and radiographer's assistants at the interval specified in the NRC Byproduct Material License, and by creating false records for audits which he did not conduct, thus making the record appear as though a field audit was performed at the specified interval. Mr. Berna also engaged in deliberate misconduct when he requested two ARSOs to falsify field audit records. Mr. Berna engaged in additional misconduct when he told an NRC inspector that field audits of radiographers or radiographer's assistants were unannounced. Mr. Berna's actions caused the Licensee to be in violation of the Amoco License, as well as 10 CFR 30.9, and constituted violations of 10 CFR 30.10 of the Commission's regulations. As the Licensee's RSO, Mr. Berna supervised the radiation safety program associated with NRC Byproduct Material License No. 13–00155–10 and was responsible for ensuring that the Commission's regulations and license conditions were met.

Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public will be protected if Mr. Berna were permitted at this time to be involved in NRC-licensed activities. Therefore, the public health, safety and interest require that Mr. Berna be prohibited from any involvement in NRC-licensed activities for a period of three years from the date of this Order. Additionally, Mr. Berna is required to notify the NRC of his first employment in NRC-licensed activities licensed by the NRC following the prohibition period. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of Mr. Berna's conduct described above is such that the public health, safety and interest require that this Order be immediately effective. A longer period was not imposed because of the issuance of the December 1, 1992 Confirmatory Order Modifying License (Effective Immediately).

IV

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 10 CFR Part 30, and 10 CFR Part 34, it is hereby ordered, effective immediately, that:

A. Michael J. Berna is prohibited for three years from the date of this Order from engaging in NRC-licensed activities. NRC-licensed activities are conducted pursuant to a specific or general license issued by the NRC, including, but not limited to, those activities of Agreement State licensees conducted pursuant to the authority granted by 10 CFR 150.20.

B. The first time Mr. Berna is employed in NRC-licensed activities following the three-year prohibition, he shall, within 20 days of his acceptance of the employment offer involving NRC-licensed activities, notify the Director, Office of Enforcement, U.S. Nuclear Regional Administrator, NRC Region III. The notice shall include the name, address, and telephone number of the employer of the entity where he is, or will be, involved in the NRC-licensed activities. In the first notification, Mr. Berna shall include a statement of his commitment to compliance with regulatory requirements and the basis why the Commission should have confidence that he will now comply with applicable NRC requirements.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. Berna of good cause.

V

In accordance with 10 CFR 2.202, Mr. Berna must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing within 20 days of the date of this Order. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Mr. Berna or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555; to the Assistant General Counsel for Hearings and Enforcement at the same address; to the Regional Administrator, Region III, U.S. Nuclear Regulatory Commission, 801 Warrenville Road, Lisle, Illinois 60532–4351; and to Mr. Berna, if the answer or hearing request is by a person other than Mr. Berna. If a person other than Mr. Berna requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by Mr. Berna or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), Mr. Berna, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. An answer or a request for hearing shall not stay the immediate effectiveness of this order.

Dated at Rockville, Maryland this 15th day of November 1994.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,

Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support.

[FR Doc. 94–28908 Filed 11–22–94; 8:45 am]

BILLING CODE 7590–01–M

[IA 94–033]

Jeffrey DeArmond; Order Prohibiting Involvement in NRC Licensed Activities (Effective Immediately)

I

Amoco Oil Company (Amoco or Licensee) was the holder of Byproduct Material License No. 13–00155–10 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 34. The license authorized the use of byproduct material (iridium-192 and cobalt-60) for industrial radiography in devices approved by the NRC or an Agreement State. The facility where licensed materials were authorized for use and storage was located at 2815 Indianapolis Boulevard, Whiting, Indiana. The use of licensed material was authorized at temporary job sites anywhere in the United States where the United States Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material. The License was originally issued on February 4, 1958, and was terminated on October 19, 1993.

Mr. DeArmond performed duties as an Assistant Radiation Safety Officer (ARSO) for the Licensee until he was relieved of these duties on October 16, 1992.

II

On July 27, 1992, the NRC Region III office received information that the Licensee's Radiation Safety Officer (RSO), had not conducted field audits of radiographers and radiographer's assistants as required by license conditions and that he fabricated reports for the audits that he did not perform by documenting that audits had been performed. The NRC conducted an inspection at the Licensee's Whiting, Indiana, refinery from September 15 to October 9, 1992. The NRC Office of Investigations (OI) subsequently conducted an investigation. The Licensee conducted an investigation contemporaneously with the NRC inspection and investigation. Deliberate violations of NRC requirements were

identified as a result of the NRC inspection and the investigation.

Condition 18.A of License No. 13–00155–10 incorporates the statements, representations, and procedures contained in the license application dated March 28, 1990. Item 10.3 of that application required, in part, that practicing radiographers and radiographer's assistants are to be audited at intervals not to exceed 3 months to meet the requirements of 10 CFR Part 34 and the Licensee's Operating and Emergency Procedures. Item 10.5 of that application required, in part, that certain records be generated and maintained, including a record of the quarterly audits of radiographers and radiographer's assistants.

Testimony provided by Mr. DeArmond on November 5, 1992 indicated that at the request of the RSO on or about September 15, 1992, Mr. DeArmond falsified at least two records of audits of radiographers and radiographer's assistants for May 1992 by generating records for audits that were not performed. This is contrary to the audit requirements established by Item 10.3 and the record generation and maintenance requirements established by Item 10.5 of the license application incorporated into the License as Condition No. 18; and caused the License to be in violation of 10 CFR 30.9(a) and constituted a violation of 10 CFR 30.10(a) of the Commission's regulations.

The Licensee conducted an internal investigation and based on the results of its investigation the Licensee suspended Mr. DeArmond's employment for two weeks without pay.

III

Based on the above, it appears that Mr. DeArmond engaged in deliberate misconduct during September 1992, when at the request of the RSO, Mr. DeArmond created false field audit records of radiographers and radiographer's assistants for audits which had not been performed, thus making the record appear as though a field audit was performed at the specified interval. Mr. DeArmond's actions caused the Licensee to be in violation of Items 10.3 and 10.5 of the license application incorporated into the License as Condition No. 18 and 10 CFR 30.9, and constituted a violation of 10 CFR 30.10 of the Commission's regulations. As an ARSO, Mr. DeArmond supervised the radiation safety program associated with NRC Byproduct Material License No. 13–00155–10 and Mr. DeArmond was responsible for ensuring that the Commission's regulations and license conditions were met.

Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public will be protected if Mr. DeArmond were permitted at this time to be involved in NRC-licensed activities. Therefore, the public health, safety and interest require that Mr. DeArmond be prohibited from any involvement in NRC-licensed activities for a period of one year from the date of this Order. Additionally, Mr. DeArmond is required to notify the NRC of his first employment in NRC-licensed activities licensed by the NRC following the prohibition period. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of Mr. DeArmond's conduct described above is such that the public health, safety and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 10 CFR Part 30, and 10 CFR Part 34, it is hereby ordered, effective immediately, that:

A. Jeffrey DeArmond is prohibited for one year from the date of this Order from engaging in NRC-licensed activities. NRC-licensed activities are those activities that are conducted pursuant to a specific or general license issued by the NRC, including, but not limited to, those activities of Agreement State licensees conducted pursuant to the authority granted by 10 CFR 150.20.

B. The first time Mr. DeArmond is employed in NRC-licensed activities following the one-year prohibition, he shall, within 20 days of his acceptance of the employment offer involving NRC-licensed activities, notify the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and the Regional Administrator, NRC Region III. The notice shall include the name, address, and telephone number of the employer or the entity where he is, or will be, involved in the NRC-licensed activities. In the first notification, Mr. DeArmond shall include a statement of his commitment to compliance with regulatory requirements and the basis why the Commission should have confidence that he will now comply with applicable NRC requirements.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. DeArmond of good cause.

V

In accordance with 10 CFR 2.202, Mr. DeArmond must, and any other person adversely affected by this Order may submit an answer to this Order, and may request a hearing within 20 days of the date of this Order. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Mr. DeArmond or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555; to the Assistant General Counsel for Hearings and Enforcement at the same address; to the Regional Administrator, Region III, U.S. Nuclear Regulatory Commission, 801 Warrenville Road, Lisle, Illinois 60532–4351; and to Mr. DeArmond, if the answer or hearing request is by a person other than Mr. DeArmond. If a person other than Mr. DeArmond requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by Mr. DeArmond or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), Mr. DeArmond, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. An answer or a request for hearing shall not stay

the immediate effectiveness of this order.

Dated at Rockville, Maryland this 15th day of November 1994.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,

Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support.

[FR Doc. 94–28907 Filed 11–22–94; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. 50–445 and 50–446]

Texas Utilities Electric Company; Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License Nos. NPF–87 and NPF–89, issued to Texas Utilities Electric Company (TU Electric, the licensee) for operation of the Comanche Peak Steam Electric Station, Units 1 and 2 located in Somervell County, Texas.

The proposed amendment would modify the Comanche Peak Steam Electric Station (CPSES) Technical Specification Table 4.8–1 "Diesel Generator Test Schedule," by excluding two valid failures for the Unit 2 Train B emergency diesel generator (EDG) from contributing towards an accelerated test schedule.

The CPSES Unit 2 design employs EDGs to provide onsite AC power in the event that offsite AC power is not available. The EDGs are required to be tested on a periodic basis (normally monthly) to provide an ongoing demonstration of performance and reliability. In accordance with technical specifications, EDG failures are reported to the NRC in special reports, and when certain values for the number of failures per number of valid tests (as defined by Regulatory Position C.2.e of Regulatory Guide 1.108, Revision 1) are exceeded, the frequency of testing is accelerated to weekly. Due to recent failures, technical specifications require weekly testing until the third week of December 1994 (assuming no additional failures are encountered). In its letter of November 11, 1994, TU Electric requested that the amendment be approved on an expedited basis to preclude unnecessary testing of the Unit 2 Train B EDG because such testing could result in an overall degradation of the EDG.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

Pursuant to 10 CFR 50.91(a)(6) for amendments to be granted under exigent circumstances, the NRC staff must determine that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

There are no initiating events in accidents previously evaluated that involve testing of EDGs [emergency diesel generators]. Therefore, deletion of accelerated testing of EDGs does not involve a significant increase in the probability of an accident previously evaluated.

A reduction in the number of test starts decreases EDG component stress and wear and decreases unavailability time for maintenance and pre and post run checks. The resulting change in EDG reliability and availability is an improvement toward ensuring the EDGs are capable of fulfilling their functional requirement to provide electric power for safe shutdown of the plant during loss of offsite power. The failure mode that caused the failures being excluded have been eliminated with the result that their impact on future reliability has likewise been eliminated. Therefore, deletion of accelerated testing of EDGs does not involve a significant increase in the consequences of an accident previously evaluated.

The end result of this technical specification change is to prevent unnecessary testing. As such, this action does not impact the probability of an accident. It only impacts the consequences of an accident positively by eliminating unnecessary testing which could reduce the reliability of the Diesel Generator; and therefore this Technical Specification change does not significantly increase the probability or consequences of an accident.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluate?

The frequency at which EDG testing occurs does not affect the potential failure modes of the EDGs, which have already been assessed in the CPSES design. Therefore, a reduction in accelerated testing of EDGs does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

The margin of safety impact associated with accelerated testing relates to EDG reliability and availability. A reduction in the number of test starts decreases EDG component stress and wear and decreases unavailability time for maintenance and pre and post run checks. The resulting change in EDG reliability and availability is an improvement toward ensuring the EDGs are capable of fulfilling their functional requirement to provide electric power for safe shutdown of the plant during loss of offsite power. Therefore, a reduction in the accelerated testing of EDGs does not involve a significant reduction in a margin of safety.

Avoiding unnecessary testing has no impact on failure points and will reduce the likelihood of Diesel Generator failure when the engine is needed to perform a safety function. As a result, the requested technical specification change does not significantly reduce the margin of safety. This technical specification change does not constitute a significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.29(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 15 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 15-day notice period. However, should circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 15-day notice period, provided that its final determination is that the

amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives, Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By December 28, 1994, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC, and at the local public document room located at the University of Texas at Arlington Library, Government Publications/Maps, 702 College, P.O. Box 19497, Arlington, Texas 76019. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularly the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participation as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If the amendment is issued before the expiration of the 30-day hearing period, the Commission will make a final determination on the issue of no significant hazards consideration. If a hearing is requested, the final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union 1–(800) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to William D. Beckner, Director, Project Directorate IV–1: Petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to George L. Edgar, Esq., Newman and Holtzinger, 1615 L Street, N.W., Suite 1000, Washington, D.C. 20036, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated November 11, 1994, which is available for public inspection at the Commission's Public Document

Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room, located at the University of Texas at Arlington Library, Government Publications/Maps, 702 College, P.O. Box 19497, Arlington, Texas 76019.

Dated at Rockville, Maryland, this 17th day of November 1994.

For the Nuclear Regulatory Commission.

Timothy J. Polich,

Project Manager, Project Directorate IV–I, Division of Reactor Projects III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 94–28910 Filed 11–22–94; 8:45 am]

BILLING CODE 7590–01–M

RESOLUTION TRUST CORPORATION

Coastal Barrier Improvement Act; Property Availability; Shannondale Property, Jefferson County, WV

AGENCY: Resolution Trust Corporation.

ACTION: Notice.

SUMMARY: Notice is hereby given that the property known as Shannondale, located in Kabletown District, Jefferson County, West Virginia, is affected by Section 10 of the Coastal Barrier Improvement Act of 1990 as specified below.

DATES: Written notices of serious interest to purchase or effect other transfer of all or any portion of this property may be mailed or faxed to the RTC until February 21, 1995.

ADDRESSES: Copies of detailed descriptions of this property, including maps, can be obtained from or are available for inspection by contacting the following person: Mr. Dan Hummer, Resolution Trust Corporation, Atlanta Field Office, 245 Peachtree Center Avenue, NE., Marquis One Tower, 10th Floor, Atlanta, GA 30303, (404) 230–6594; Fax (404) 225–5092.

SUPPLEMENTARY INFORMATION: The Shannondale property is located on the east side of Mission Road (State Route 9/5) and south of Highway 9, in Kabletown District, Jefferson County, West Virginia. The site consists of approximately 740.53 acres of undeveloped wooded land. The Shannondale property has recreational value and is adjacent to the Appalachian National Scenic Trail which is managed by the National Park Service for recreational purposes. This property is covered property within the meaning of Section 10 of the Coastal Barrier Improvement Act of 1990, Pub L. 101–591 (12 U.S.C. 1441a–3).

Written notice of serious interest in the purchase or other transfer of all or any portion of this property must be received on or before February 21, 1995 by the Resolution Trust Corporation at the appropriate address stated above.

Those entities eligible to submit written notices of serious interest are:

51. Agencies or entities of the Federal government;

52. Agencies or entities of State or local government; and

53. "Qualified organizations" pursuant to section 170(h)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 170(h)(3)).

Written notices of serious interest must be submitted in the following form:

NOTICE OF SERIOUS INTEREST

RE: [insert name of property]

Federal Register Publication Date: November 23, 1994.

1. Entity name.

2. Declaration of eligibility to submit Notice under criteria set forth in the Coastal Barrier Improvement Act of 1990, P.L. 101–591, section 10(b)(2), (12 U.S.C. 1441a–3(b)(2)), including, for qualified organizations, a determination letter from the United States Internal Revenue Service regarding the organization's status under section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 170(h)(3)).

3. Brief description of proposed terms of purchase or other, offer for all or any portion of the property (e.g., price, method of financing, expected closing date, etc.).

4. Declaration of entity that it intends to use the property for wildlife refuge, sanctuary, open space, recreational, historical, cultural, or natural resource conservation purposes (12 U.S.C. 1441a–3(b)(4)), as provided in a clear written description of the purpose(s) to which the property will be put and the location and acreage of the area covered by each purpose(s) including a declaration of entity that it will accept the placement, by the RTC, of an easement or deed restriction on the property consistent with its intended conservation use(s) as stated in its notice of serious interest.

5. Authorized Representative (Name/Address/Telephone/Fax).

List of Subjects

Environmental protection.

Dated: November 16, 1994.

Resolution Trust Corporation.

William J. Tricarico,

Assistant Secretary.

[FR Doc. 94–28906 Filed 11–22–94; 8:45 am]

BILLING CODE 6714–01–M

SECURITIES AND EXCHANGE COMMISSION

Requests Under Review by Office of Management and Budget

Acting Agency Clearance Office: Richard T. Redfearn, (202) 942–8800.

Upon written request copy available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, D.C. 20549.

Extensions: Rule 17Ad–11, Rule 17Ad–13, File No. 270–261, File No. 270–263.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (Commission) has submitted to the Office of Management and Budget requests for approval of extension on previously approved collections for the following rules:

Rule 17Ad–11 requires registered transfer agents to report to issuer and the appropriate regulatory agency aged record differences, buy-ins, and failure to post certificate detail to master securityholder and subsidiary files. Approximately 150 respondents incur an estimated average of one half burden hour to comply with the rule.

Rule 17Ad–13 requires certain registered transfer agents to file annually with the Commission and the appropriate regulatory agency, a study and evaluation prepared by an independent accountant concerning the transfer agent's system of internal accounting control and related procedures for the transfer of record ownership and the safeguarding of related securities and funds. Approximately 200 respondents incur an estimated average of 175 burden hours to comply with the rule.

Direct general comments to the Clearance Officer for the Securities and Exchange Commission at the address below. Direct any comments concerning the accuracy of the estimated burden hours for compliance with the Commission rules and forms to Richard T. Redfearn, Acting Director, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, D.C. 20549 and Clearance Officer for the Securities and Exchange Commission, (Project Number 3235–0274 and 3235–0275), Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Dated: November 14, 1994.

Jonathan G. Katz,

Secretary.

[FR Doc. 94–28864 Filed 11–22–94; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–34979; File No. SR–NASD–94–42]

Self-Regulatory Organizations; Order Approving Proposed Rule Change by National Association of Securities Dealers, Inc., Relating to Amendments to the Examination Specifications and Study Outline for the Assistant Representative-Order Processing (Series 11) Examination

November 16, 1994.

On July 26, 1994, the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("SEC" or "Commission") a proposed rule change [1] pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [2] and Rule 19b–4 thereunder.[3] The rule change amends the examination specification and study outline for the Assistant Representative-Order-Processing ("Series 11") qualifications examinations. Specifically, the filing revises materials pertaining to appropriate job functions, and includes new material pertaining to recently effective rules and regulations affecting the securities industry. The number of questions per examination and the examination time are unaffected by the amendments.

The Commission published notice of the proposed rule change in the **Federal Register** on August 23, 1994.[4] No comments were received in response to the Notice. For the reasons discussed below, the Commission is approving the proposed rule change.

The NASD periodically reviews the content of its qualification examination specifications, and study outline to determine whether amendments are necessary or appropriate in view of changes pertaining to the subject matter covered by the examinations. The amendments to the Series 11 examination specifications, and study outline are designed to further test appropriate job functions and to reflect changes in the rules and regulations affecting the securities industry. The proposed rule change will be effective 60 days from the date of this order.

The Commission finds the proposed rule change consistent with the provisions of Section 15A(g)(3) of the Act.[5] Section 15A(g)(3) provides, among other things, that a registered securities association may require that its members and their associated persons meet certain training, experience and competence standards. The Commission finds that the proposed changes to the examination specification and study outline will help ensure that persons seeking registration in the securities industry have attained the requisite levels of knowledge and competence.

It is therefore ordered, Pursuant to Section 19(b)(2) of the Act, that the proposed rule change SR–NASD–94–42 be, and hereby is, approved, effective on January 17, 1995.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Jonathan G. Katz,

Secretary.

[FR Doc. 94–28865 Filed 11–22–94; 8:45 am]

BILLING CODE 8010–01–M

[Investment Company Act Rel. No. 20710; 812–9084]

Connecticut Mutual Investment Accounts, Inc., et al.; Notice of Application

November 17, 1994.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 ("Act").

APPLICANTS: Connecticut Mutual Investment Accounts, Inc (including all existing and future series thereof) (the "Fund"), and G.R. Phelps & Co., Inc. ("Phelps"), on their own behalf and on behalf of any registered open-end investment companies (including any series thereof) for which Phelps or any person controlling, controlled by, or under common control with Phelps serves in the future as investment adviser or distributor (collectively, the "Fund").

RELEVANT ACT SECTIONS: Exemption requested under section 6(c) from the provisions of sections 2(a) (32), 2(a)(35), 18(f), 18(g), 18(i), 22(c), and 22(d), and rule 22c–1 thereunder.

SUMMARY OF APPLICATION: Applicants seek an order that would permit the Funds to issue an unlimited number of classes of shares representing interests in the same portfolio of securities, assess a contingent deferred sales load ("CDSL") on certain redemptions of shares, and waive the CDSL in certain instances.

FILING DATE: The application was filed on July 1, 1994, and amended on September 19, 1994 and November 16, 1994.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on December 12, 1994, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request such notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, D.C. 20549. Applicants, 140 Garden Street, Hartford, Connecticut 06154.

FOR FURTHER INFORMATION CONTACT: Courtney S. Thornton, Senior Attorney, at (202) 942–0583, or Barry D. Miller, Senior Special Counsel, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. The Fund, a Maryland corporation, is a registered open-end management investment company, which currently consists of ten series. Each of the series has a separate investment objective and policies, and separate assets.

2. Phelps, a registered investment adviser and a registered broker/dealer, is an indirect wholly-owned subsidiary of Connecticut Mutual Life Insurance Company ("Connecticut Mutual"). Phelps is the investment adviser to five series of the Fund, and the distributor of the Fund's shares.[1]

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[1] The NASD subsequently filed two amendments to its original filing. In the first amendment, filed on August 1, 1994, the NASD filed amended examination specifications for this registration category. On August 31, 1994, the NASD provided the examination question bank for the Series 11 examination. Both filings were made pursuant to a NASD request for non-public treatment.

[2] 15 U.S.C. 78s(b)(1).

[3] 17 CFR 240.19b–4.

[4] Securities Exchange Act Release No. 34534 (August 16, 1994), 59 FR 43367.

[5] 15 U.S.C. 78*o*–3(g)(3).

[6] 17 CFR 200.30–3(a)(12).

[1] Five new series of the Fund (the "New Accounts"), which commenced operations on October 3, 1994, are distributed, but not advised, by

3. Shares of the single existing class of the Fund (the "Non-Money Market Series"), except shares of the money market series (the "Money Market Series"), are sold at net asset value plus a front-end sales load. In accordance with the terms of a prior exemptive order,[2] purchases of shares of the Non-Money Market Series in amounts of $500,000 or more are not subject to a front-end sales load, but instead are subject to a CDSL of 1% on redemptions of such shares within twelve months after purchase. Shares of the Money Market Series are sold at net asset value with no sales load. In addition, the Fund has adopted distribution plans pursuant to rule 12b–1 under the Act (the "Distribution Plans"); to date, only the shareholders of the Money Market Series and the initial shareholder of each New Account have approved the Distribution Plans.

4. Applicants propose to establish a multiple class distribution system (the "Multiple Class System"), which would permit the Funds to issue an unlimited number of classes of shares. These classes would differ in the following respects: (a) the impact of certain class expenses (as set forth in condition 1 below) ("Class Expenses"); (b) expenses payable under a Distribution Plan, a service fee paid to institutions for the provision of certain account administration and shareholder liaison services to their customers pursuant to a non-rule 12b–1 shareholder services plan ("Shareholder Services Plan"), and/or an administration fee paid to institutions for the provision of certain account administration services to their customers pursuant to a non-rule 12b–1 administration plan (an "Administration Plan") (collectively, the "Plans" and "Plan Payments"); (c) voting rights related to any Plan; (d) exchange privileges; (e) the conversion feature; (f) class designations; and (g) any other additional incremental expenses subsequently identified that could be properly allocated to one class, as permitted by the SEC pursuant to an amended order. Under the Multiple Class System, the Funds will be authorized to sell shares of different classes under different sales arrangements, including sales with a front-end sales charge, subject to a CDSL, a combination of a front-end sales load and a CDSL, or at net asset value.

5. Under a Distribution Plan, shares of an affected class would bear the cost of selling and servicing such shares. The distribution fees under such a Plan would be payable to reimburse or compensate the Fund's distributor for expenses that primarily are intended to result in the sale of the class shares. The service fees under a Distribution Plan would be payable to reimburse or compensate the Fund's distributor, securities dealers, and other institutions for personal services and maintenance of shareholder accounts, and any additional service-related expenses.

6. Under a Shareholder Services Plan, a Fund (or the distributor) enters into service agreements with affiliated and unaffiliated financial institutions, broker-dealers, and securities professionals ("Service Organizations") concerning the provision of account administration services ("Account Administration Services"), and certain other services[3] to customers of the Service Organizations who beneficially own class shares offered pursuant to such Plan. Under its Shareholder Services Plan, the Fund would pay a Service Organization for its services and assistance in accordance with the terms of the Plan and its particular service agreement.

7. Under an Administration Plan, the Fund (or its distributor) enters into service agreements with Service Organizations for the provision of Account Administration Services to the customers of such Service Organizations who beneficially own class shares offered pursuant to such Plan. Under its Administration Plan, the Fund would pay a Service Organization a fee for its services and assistance in accordance with the terms of the Administration Plan and its particular service agreement. The expense of such payments would be borne entirely by the beneficial owners of class shares.

8. The provision of services under the Plans will augment (and not be duplicative of) the services to be provided to the Fund by its investment adviser, transfer agent, and custodian.

9. The Funds may establish classes of shares that will be available only for investment by one or more of the following categories of investors: (a) unaffiliated benefit plans; (b) tax-exempt retirement plans of Connecticut Mutual and its affiliates; (c) unit investment trusts sponsored by Phelps or entities controlling, controlled by, or under common control with Phelps; (d) banks and insurance companies that are not affiliated with a Fund's adviser, subadviser, manager, administrator or principal underwriter purchasing for their own accounts; (e) investment companies not affiliated with a Fund's adviser, subadviser, manager, administrator, or principal underwriter; and (f) endowment funds of non-profit organizations that are not affiliated with a Fund's adviser, subadviser, manager, administrator or principal underwriter (each class, a "Limited Institutional Class"). Shares of a Limited Institutional Class will be available only to the above categories of institutional investors. A series may elect not to offer shares of a Limited Institutional Class to one or more of these categories of institutional investors. However, if a series elects to offer shares of any Limited Institutional Class to any category of investors, such investors will not be permitted to invest in shares of any other class of such series.

10. The unaffiliated benefit plans in category (a) will include qualified retirement plans, with respect to which a trustee is vested with investment discretion as to plan assets, other than individual retirement accounts and self-employed retirement plans, and will have limitations on the ability of plan beneficiaries to access their plan investments without incurring adverse tax consequences. Applicants will exclude self-directed plans from this category.

11. Appropriate exemptive relief will be sought from the SEC prior to any investment by UITs in category (c) in shares of a Limited Institutional Class of the Fund.

12. All exchanges will comply with the provisions of rule 11a–3 under the Act.

13. Certain expenses may be attributable to the Fund, but not to a particular series thereof ("Fund Expenses"). All such Fund Expenses may be allocated among the series of the Fund based on the relative aggregate net assets of such series or on such other basis as the board of directors may from time to time approve. Expenses that are attributable to a particular series or to an investment company with only one series, but not a particular class thereof, will be allocated daily to each class

Phelps. Each New Account invests substantially all of its assets in another registered investment company advised by an unaffiliated investment adviser (in what is commonly referred to as a "master/feeder" structure).

[2] *Connecticut Mutual Investment Accounts, Inc., et al.*, Investment Company Act Release Nos. 19374 (Mar. 31, 1993) (notice) and 19435 (Apr. 27, 1993) (order). Any order issued on this application will supersede the prior order.

[3] These additional services would include, but not be limited to, receiving and answering investor correspondence, including requests for prospectuses, statements of additional information and shareholder reports; assisting customers in completing application forms, selecting dividend and other account options, and opening custody accounts with the Service Organization; and acting as a liaison between customers and the Fund, including obtaining information from the Fund, working with the Fund to correct errors and resolve problems, and providing statistical and other information to the Fund.

based on the percentage that the net asset value of such class represents of the total of all classes of shares of such series. Payments under the Plans and Class Expenses will be allocated to the shares of the class to which they are attributable.

14. A conversion feature, after the expiration of a specified period, will automatically convert shares of one class at their net asset value to shares of another class with different features, as set forth in condition 15 below. For purposes of the conversion, all shares in a shareholder's account that were acquired through the reinvestment of dividends and other distributions paid in respect of such shares (and which had not yet converted) will be considered to be held in a separate subaccount. Each time any shares in the shareholder's account convert, an equal *pro rata* portion of shares in the subaccount also will convert and no longer will be considered held in the subaccount. The portion will be determined by the ratio that the shareholder's converting shares bears to the shareholder's total shares subject to the conversion feature, but excluding shares held in the subaccount.

15. Any conversion of shares will be subject to the continuing availability of an opinion of counsel or a private letter ruling from the Internal Revenue Service to the effect that the conversion of shares does not constitute a taxable event under federal income tax law. Conversion of shares might be suspended if such an opinion or ruling were no longer available.

16. Applicants propose that the Funds be permitted to assess CDSLs on certain redemptions and repurchases of shares comprising a distinct class or particular shares within a class. Under the proposed CDSL arrangement, the amount of a CDSL charged to a shareholder would depend on the time that had elapsed since the shareholder purchased the CDSL shares. Any CDSL would be imposed on the lesser of (a) the net asset value of the redeemed shares at the time of purchase, or (b) the net asset value of the redeemed shares at the time of redemption. No CDSL would be imposed with respect to: (a) the portion of redemption proceeds attributable to increases in the value of an account above the net cost of the investment due to increases in the net asset value per share; (b) shares acquired through reinvestment of income dividends or capital gain distributions; or (c) CDSL shares held for more than a specified term after the end of the calendar period used to determine the period in which the purchase order for such shares was accepted. In determining whether a CDSL were payable, it would be assumed that shares, or amounts representing shares, that were not subject to a CDSL were redeemed first, and that other shares or amounts were then redeemed in the order purchased.

17. The aggregate of any front-end sales load, an asset-based sales charge, and any CDSL would be subject to the limitation imposed by section 26(d) of Article III of the Rules of Fair Practice of the National Association of Securities Dealers ("NASD").

18. Applicants intend to waive or reduce the CDSL in certain circumstances described in the prospectus or prospectuses of the Funds. If a Fund waives or reduces the CDSL, such waiver or reduction will be uniformly applied to all shares in the specified category. In waiving or reducing a CDSL, the Fund will comply with the requirements of rule 22d–1 under the Act.

Applicants' Legal Analysis

1. Applicants request an exemptive order to the extent that the proposed issuance and sale of an unlimited number of classes of shares representing interests in the Fund might be deemed: (a) to result in a "senior security" within the meaning of section 18(g) of the Act and to be prohibited by section 18(f)(1); and (b) to violate the equal voting provisions of section 18(i).

2. Section 18 is intended to prevent investment companies from borrowing excessively and issuing excessive amounts of senior securities, which increase the speculative character of their junior securities, or from operating without adequate assets or reserves. The Multiple Class System does not involve borrowings and does not affect the Funds' existing assets or reserves. In addition, the proposed arrangement will not increase the speculative character of the shares of the Funds, since each class of shares will participate in all of the Funds' appreciation (if any), income, and all of the Funds' expenses (with the exception of the Plan Payments and Class Expenses).

3. Applicants believe that the proposed allocation of Class Expenses in the manner described above and the voting rights relating to the Plans is equitable and would not discriminate unfairly against any group of shareholders. Because, with respect to any Fund, the rights and privileges of each class of shares are substantially identical, the possibility that their interests would ever conflict would be remote. In any event, the interests of the affected shareholders with respect to Plan Payments would be adequately protected since Plans for each of those classes will conform to the requirements of rule 12b–1 (except that a Shareholder Services Plan or an Administration Plan may not confer certain voting rights), including the requirement that their implementation and continuance be approved on an annual basis by both the full board and the non-interested directors of a Fund.

4. Applicants also request an exemption from sections 2(a)(32), 2(a)(35), 22(c), and 22(d) of the Act, and rule 22d–1 thereunder, to the extent necessary to permit the Funds to assess a CDSL on certain redemptions. Applicants believe that the implementation of the CDSL as described above would be fair and would be in the public interest and the interests of the shareholders of the Funds, and would be consistent with the protection of investors and the purposes fairly intended by the provisions of the Act.

Applicants' Conditions

Applicants agree that any order of the SEC granting the requested relief will be subject to the following conditions:

1. Each class of shares will represent interests in the same portfolio of investments of a Fund or a series, and be identical in all respects except as set forth below. The only differences among the classes of shares of a Fund will relate solely to: (a) the impact of certain Class Expenses, which shall be limited to: (i) transfer agency fees (including the incremental cost of monitoring any CDSL) attributable to a specific class of shares; (ii) expenses related to preparing, printing, mailing and distributing materials such as shareholder reports, newsletters, prospectuses and proxy statements to current shareholders of a specific class; (iii) SEC, state, and foreign jurisdiction registration fees incurred by a specific class of shares; (iv) the expenses of administrative personnel and services required to support the shareholders of a specific class (including, but not limited to, maintaining telephone lines and personnel to answer shareholders' inquiries about their accounts or about the Fund); (v) litigation or other legal expenses relating to a class of shares; (vi) directors' fees or expenses incurred as a result of issues relating to a specific class of shares; and (vii) accounting, audit and tax expenses relating to a specific class of shares; (b) expenses payable by a class pursuant to a Plan with respect to such class; (c) the voting rights related to any Plan affecting a specific class of shares, except as provided in condition 16 below; (d) exchange privileges; (e) the conversion

feature; (f) class designations; and (g) any other additional incremental expenses subsequently identified that could be properly allocated to one class, which shall be approved or permitted by the SEC pursuant to an amended order.

2. The directors of a Fund, including a majority of the non-interested directors, will approve the Multiple Class System. The minutes of the meetings of the directors of a Fund regarding the deliberations of the directors concerning, and their approval of, the Multiple Class System will reflect in detail the reasons for the directors' determination that the proposed Multiple Class System is in the best interests of both the Fund and its shareholders.

3. The initial determination of Class Expenses that will be allocated to a class, and any subsequent changes thereto, will be reviewed and approved by a vote of the directors, including a majority of the non-interested directors. Any persons authorized to direct the allocation and disposition of monies paid or payable by a Fund to meet Class Expenses shall provide to the directors, and the directors shall review at least quarterly, a written report of the amounts so expended and the purposes for which such expenditures were made.

4. Any distributor will adopt compliance standards as to when each class of shares may appropriately be sold to particular investors. Applicants will require all persons selling shares of a Fund to agree to conform to such standards. Such compliance standards will require that all investors eligible to purchase shares of a Limited Institutional Class be sold only shares of the Limited Institutional Class, rather than any other class of shares offered by the Fund.

5. The Shareholder Services Plans and Administration Plans will be adopted and operated in accordance with the procedures set forth in rule 12b–1(b) through (f) as if the expenditures made thereunder were subject to rule 12b–1, except that shareholders need not enjoy the voting rights specified in rule 12b–1.

6. On an ongoing basis, the directors of a Fund, pursuant to their fiduciary responsibilities under the Act and otherwise, will monitor the Fund for the existence of any material conflicts among the interests of the classes of shares. The directors, including a majority of the non-interested directors, will take such action as is reasonably necessary to eliminate any such conflicts that may develop. The investment adviser and distributor will be responsible for reporting any potential or existing conflicts to the directors. If a conflict arises, the investment adviser and the distributor, each at its own cost, will remedy such conflict up to and including establishing a new registered management investment company.

7. The directors will receive quarterly and annual statements concerning the amounts expended under each Shareholder Services, Administration and Distribution Plan and the related Service Agreement complying with paragraph (b)(3)(ii) of rule 12b–1, as it may be amended from time to time, for the Fund. In the statements, only expenditures properly attributable to the sale or servicing of a particular class of shares will be used to justify any distribution or servicing fee charged to that class. Expenditures not related to the sale or servicing of a particular class will not be presented to the directors to justify any fee attributable to that class. The statements, including the allocations upon which they are based, will be subject to the review and approval of the non-interested directors in the exercise of their fiduciary duties.

8. Dividends paid by a Fund with respect to each class of its shares, to the extent any dividends are paid, will be calculated in the same manner, at the same time, on the same day, and will be paid in the same amount, except that Plan Payments and any Class Expenses will be borne exclusively by the affected class.

9. The methodology and procedures for calculating the net asset value and dividends and distributions of the classes of shares and the proper allocation of expenses among the classes have been reviewed by an expert (the "Expert"). The Expert has rendered a report to applicants that such methodology and procedures are adequate to ensure that such calculations and allocations will be made in an appropriate manner. On an ongoing basis, the Expert, or an appropriate substitute Expert, will monitor the manner in which the calculations and allocations are being made and, based upon such review, will render at least annually a report to the Fund that the calculations and allocations are being made properly. The reports of the Expert will be filed as part of the periodic reports filed with the SEC pursuant to sections 30(a) and 30(b)(1) of the Act. The work papers of the Expert with respect to such reports, following a request by a Fund (which the Fund agrees to provide), will be available for inspection by the SEC staff upon the written request for such work papers by a senior member of the Division of Investment Management or of a regional office of the SEC limited to the Director, an Associate Director, the Chief Accountant, the Chief Financial Analyst, an Assistant Director, and any Regional Administrators or Associate and Assistant Administrators. The initial report of the Expert is a "report on the policies and procedures placed in operation," and the ongoing reports will be "reports on policies and procedures placed in operation and tests of operating effectiveness" as defined and described in SAS No. 70 of the American Institute of Certified Public Accountants ("AICPA"), as it may be amended from time to time, or in similar auditing standards as may be adopted by the AICPA from time to time.

10. Applicants have adequate facilities in place to ensure implementation of the methodology and procedures for calculating the net asset value and dividends and distributions of the classes of shares and the proper allocation of expenses among the classes of shares, and this representation has been concurred with by the Expert in the initial report referred to in the immediately preceding condition and will be concurred with by the Expert, or an appropriate substitute Expert, on an ongoing basis at least annually in the ongoing reports referred to in the immediately preceding condition. Applicants agree to take immediate corrective action if this representation is not concurred in by the Expert or appropriate substitute Expert.

11. The prospectus of the Fund, or if applicable, the prospectus of each class of shares of the Fund, will include a statement to the effect that any person entitled to receive compensation for selling or servicing Fund Shares may receive different compensation with respect to one particular class of shares over another in the Fund.

12. The conditions pursuant to which the exemptive order is granted and the duties and responsibilities of the directors of the Fund with respect to the Multiple Class System will be set forth in guidelines, which will be furnished to the directors.

13. The Fund will disclose the respective expenses, performance data, distribution arrangements, services, fees, sales loads, deferred sales loads, and exchange privileges applicable to each class of shares, other than the Limited Institutional Class, in every prospectus, regardless of whether all classes of shares are offered through each prospectus. The Limited Institutional Class will be offered solely pursuant to a separate prospectus. The prospectus for the Limited Institutional

class will disclose the existence of the Fund's other classes, and the prospectus for the Fund's other classes will disclose the existence of the Limited Institutional Class, and will identify the persons eligible to purchase shares of such class. The Fund will disclose the respective expenses and performance data applicable to all classes of shares in every shareholder report. The shareholder reports will contain, in the statement of assets and liabilities and statement of operations, information related to the Fund as a whole generally and not on a per class basis. The Fund's per share data, however, will be prepared on a per class basis with respect to all classes of shares of the Fund. To the extent any advertisement or sales literature describes the expenses or performance data applicable to any class of shares, it will also disclose the respective expenses and/or performance data applicable to all classes of shares, except the Limited Institutional Class. Advertising materials reflecting the expenses or performance data for the Limited Institutional Class will be available only to those persons eligible to purchase the Limited Institutional Class. The information provided by applicants for publication in any newspaper or similar listing of the Fund's net asset value and public offering price will present each class of shares, except the Limited Institutional Class, separately.

14. Applicants acknowledge that the grant of the relief requested by this application will not imply SEC approval, authorization or acquiescence in any particular level of payments that a Fund may make pursuant to the Distribution, Administration, or Shareholder Services Plans in reliance on the exemptive order.

15. Any class of shares ("Purchase Class") with a conversion feature will convert into another class of shares ("Target Class") on the basis of the relative net asset values of the two classes, without the imposition of any sales load, fee, or other charge. After conversion, the converted shares will be subject to an asset-based sales load and/or service fee (as those terms are defined in Article III, Section 26 of the NASD's Rules of Fair Practice), if any, that in the aggregate are lower than the asset-based sales load and service fee to which they were subject prior to the conversion.

16. If a Fund implements any amendment to its Distribution Plan (or, if presented to shareholders, adopts or implements any amendment of the non-rule 12b–1 Shareholder Services Plan or Administration Plan) that would increase materially the amount that may be borne by the Target Class shares under the plan, existing Purchase Class shares will stop converting into Target Class unless the Purchase Class shareholders, voting separately as a class, approve the proposal. If such approval is not granted, the directors shall take such action as is necessary to ensure that existing Purchase Class shares are exchanged or converted into a new class of shares ("New Target Class"), identical in all material respects to the Target Class as it existed prior to implementation of the proposal, no later than the date such Purchase Class shares previously were scheduled to convert into Target Class shares. If deemed advisable by the directors to implement the foregoing, such action may include the exchange of all existing Purchase Class shares for a new class ("New Purchase Class"), identical to existing Purchase Class shares in all material respects except that New Purchase Class will convert into Target Class. A New Target Class or New Purchase Class may be formed without further exemptive relief. Exchanges or conversions described in this condition shall be effected in a manner that the directors reasonable believe will not be subject to federal taxation. In accordance with condition 6, any additional cost associated with the creation, exchange or conversion of New Target Class or New Purchase Class shall be borne solely by the adviser and the distributor. Purchase Class shares sold after the implementation of the proposal may convert into Target Class shares subject to the higher maximum payment, provided that the material features of the Plan and the relationship of such Plan to the Purchase Class shares are disclosed in an effective registration statement.

17. Applicants will comply with the provisions of proposed rule 6c–10 under the Act (Investment Company Act Release No. 16619 (Nov. 2, 1988)), as such rule is currently proposed, and as it may be reproposed, adopted, or amended.

For the SEC, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 94–28866 Filed 11–22–94; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Approval of Noise Compatibility Program, Central Florida Regional Airport, Sanford, FL

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the noise compatibility program submitted by the Sanford Airport Authority under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Public Law 96–193) and 14 CFR Part 150. These findings are made in recognition of the description of Federal and nonfederal responsibilities in Senate Report No. 96–52 (1980). On September 16, 1993, the FAA determined that the noise exposure maps submitted by the Sanford Airport Authority under Part 150 were in compliance with applicable requirements. On April 19, 1994, the FAA determined that the revised future noise exposure map was in compliance with applicable requirements. On October 14, 1994, the Administrator approved the Central Florida Regional Airport noise compatibility program. Twelve (12) recommendations of the program were approved and one (1) recommendation was partially approved.

EFFECTIVE DATE: The effective date of the FAA's approval of the Central Florida Regional Airport noise compatibility program is October 14, 1994.

FOR FURTHER INFORMATION CONTACT: Tommy J. Pickering, P.E., Federal Aviation Administration, Orlando Airports District Office, 9677 Tradeport Drive, Suite 130, Orlando, Florida 32827–3596, (407) 648–6583. Documents reflecting this FAA action may be reviewed at this same location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to the noise compatibility program for the Central Florida Regional Airport, effective October 14, 1994.

Under Section 104(a) of the Aviation Safety and Noise Abatement Act (ASNA) of 1979 (hereinafter referred to as "the Act"), an airport operator who has previously submitted a noise exposure map may submit to the FAA a noise compatibility program which sets forth the measures taken or proposed by the airport operator for the reduction of existing noncompatible land uses and prevention of additional noncompatible land uses within the

area covered by the noise exposure maps. The Act requires such programs to be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and FAA personnel.

Each airport noise compatability program developed in accordance with Federal Aviation Regulations (FAR) Part 150 is a local program, not a Federal program. The FAA does not substitute its judgment for that of the airport proprietor with respect to which measure should be recommended for action. The FAA's approval or disapproval of FAR Part 150 program recommendations is measured according to the standards expressed in Part 150 and the Act, and is limited to the following determinations:

a. The noise compatibility program was developed in accordance with the provisions and procedures of FAR Part 150;

b. Program measures are reasonably consistent with achieving the goals of reducing existing noncompatible land uses around the airport and preventing the introduction of additional noncompatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical users, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an airport noise compatibility program are delineated in FAR Part 150, Section 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, state, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. Where Federal funding is sought, requests for project grants must be submitted to the FAA Airports District Office in Orlando, Florida.

The Sanford Airport Authority submitted to the FAA on September 13, 1993, the noise exposure maps, descriptions, and other documentation produced during the noise compatibility planning study conducted from September 4, 1992, through April 11, 1994. The Central Florida Regional Airport noise exposure maps were determined by FAA to be in compliance with applicable requirements on September 16, 1993. A revised future noise exposure map was submitted to the FAA on March 8, 1994. The revised future noise exposure map was determined by FAA to be in compliance with applicable requirements on April 19, 1994. Notice of these determinations was published in the **Federal Register**.

The Central Florida Regional Airport study contains a proposed noise compatibility program comprised of actions designed for phased implementation by airport management and adjacent jurisdictions from the date of study completion to the year 1998. It was requested that FAA evaluate and approve this material as a noise compatibility program as described in Section 104(b) of the Act. The FAA began its review of the program on April 19, 1994, and was required by a provision of the Act to approve or disapprove the program within 180 days (other than the use of new flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program.

The submitted program contained thirteen (13) proposed actions for noise mitigation on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR Part 150 have been satisfied. The overall program, therefore, was approved by the Administrator effective October 14, 1994.

Outright approval was granted for twelve (12) of the specific program elements. One (1) program element for property acquisition was partially approved. Property acquisition associated with incompatible land uses was approved and property acquisition associated with compatible uses was disapproved. The approval action was for the following program elements:

Measure and description	NCP pages
Operational Controls	
1. Backcourse Non-Precision Approach on Runway 27R. It is recommended that a backcourse non-precision approach procedure be established on Runway 27R and that a voluntary flight procedure be established to maximize the use of an approach from the east by high performance aircraft when weather conditions permit during nighttime hours (10 p.m.—7 am). Property east of the airport is mostly undeveloped whereas property west of the airport is mostly developed and this measure can be accomplished without new equipment being installed. FAA Action: Approved. Use of this voluntary flight procedure is subject to the authority of the pilot-in-command	Pgs. VI–7 to VI–10 and Table 8.
2. GPS Approach on Runway 27R. It is recommended that when GPS equipment is available, a GPS non-precision approach procedure be established on Runway 27R. Once criteria for precision approaches is developed, it is recommended that a GPS precision approach procedure be established to Runway 27R. This will allow maximum use of an approach from the east over mostly undeveloped property. FAA Action: Approved. Use of these voluntary procedures is subject to the authority of the pilot-in-command	Pgs. VI–7 to VI–11 and Table 8.
3. Modification of Touch-and-Go Training Routes. It is recommended that the touch-and-go training routes be modified to minimize flyovers of existing elementary schools and residential areas. This would be implemented through letters to flight schools operating at the airport. FAA Action: Approved as a voluntary measure. The draft letter to flight schools shown as Appendix XI in the NCP should be modified to reflect the voluntary nature of the proposed changes in the traffic pattern	Pgs. VI–11 and VI–12, Exhibit 14A and Table 8.

Measure and description	NCP pages
4. Preferential Runway System. When the backcourse and GPS approach procedures on Runway 27R are operable, it is recommended that during nighttime hours (10 p.m.—7 am), operations east of the airport be maximized when weather and traffic conditions permit. This will reduce the number of nighttime fly-overs for communities located west of the airport. Property east of the airport is mostly undeveloped. FAA Action: Approved as a voluntary measure	Pgs. VI–12, VI–13 and Table 8.
5. Federal Noise Controls on High Performance Aircraft Engines. It is recommended that the phase out schedule for Stage 2 aircraft above 75,000 pounds through December 31, 1999, required by FAR Part 91 be supported. No further controls on aircraft specifically related to Central Florida Regional Airport are recommended. FAA Action: Approved as an expression of airport operator support for the Federal transition schedule	Pgs. VI–13 and Table 8.
6. Community Coordination Forum. The Airport Authority will establish a plan for information exchange between the Airport Authority, the City of Sanford and Seminole County to give the Airport the opportunity to review potential land use decisions and to express its views over potential incompatible development in the vicinity of the airport. FAA Action: Approved	Pgs. VI–14 and Table 8.
Land Use Controls	
1. Comprehensive Plan Modifications. It is recommended that the next updates of the Seminole County and City of Sanford Comprehensive Plans reflect the land use modifications recommended in the Part 150 Noise Compatibility Program. FAA Action: Approved	Pg. VII–11 and Table 9.
2. Land Use and Zoning. Within areas east and south of the airport it is recommended that proposed land use and zoning be modified to reflect noise compatible land uses and that the area southeast of the airport be developed with uses compatible with Airport activity. FAA Action: Approved	Pgs. VII–6 and VII–7, Exhibit 16 and Table 9.
3. Avigation Easements. It is recommended that avigation easements for the right of flight and noise exposure be required as part of any *new* site plan or subdivision approval within the 55 DNL contour. FAA Action: Approved. Section VIII of the NCP indicates that this no cost, preventive measure identifies the DNL 55dB contour for purposes of future land use planning. This is within the authority of the local land use jurisdictions	Pg. VII–1, VII–7, VIII–5 and 6, Map C, and Table 9.
4. Airport Notification. It is recommended that the Airport be notified by local governments of applications and hearing dates for changes in land use or zoning within the flight corridor area. This will allow the Airport to provide input on these requests. FAA Action: Approved	Pgs. VII–7 and Table 9.
5. Vegetative Buffers. It is recommended that a vegetative buffer with a minimum depth of 100 feet be planted along the periphery of the airport adjacent to abutting incompatible uses where FAR Part 77 requirements will allow. When the growth is mature, a 3–5 dBA reduction in peak (Lmax) noise would be anticipated. FAA Action: Approved	Pgs. VII–7 and VII–8, Exhibit 16A, and Table 9.
6. Earth Berms. It is recommended that earth berms (15–20 feet high or more) be constructed along the periphery of the airport adjacent to abutting incompatible land uses when soil material is available from other activities at the Airport and FAR Part 77 requirements will allow. Depending on the availability of fill material, a combination of berms and vegetative buffers could occur. An immediate reduction of about 5 dBA in peak noise levels (Lmax) would be provided. FAA Action: Approved	Pg. VII–8, Exhibit 16A, and Table 9.
7. Property Acquisition. It is recommended that the Sanford Airport Authority, subject to available funding from either the State of Florida or the FAA, purchase off-Airport lands within 65 DNL. This property currently includes both zoning for compatible and non-compatible development. Property acquisition would be through negotiation with the property owner, condemnation, or the development of a purchase assurance program where the Airport would agree to acquire properties at fair market value from a property owner who wishes to sell. Any homes that are acquired will be removed. Land acquisition and relocation of residents by negotiation or condemnation are governed by regulations issued under the provisions of the Uniform Relocation Assistance Act (49 CFR Part 24). Properties acquired through the purchase assurance option will involve acquisition at fair market value only. Acquired noise land will either be retained for aviation use or resold for a compatible use. Net proceeds from the resale of noise land acquired with AIP noise funds will be reimbursed to FAA or applied to other eligible noise reduction projects. FAA Action: Approved in part. Approval with respect to the acquisition of property and other measures associated with incompatible land uses within the 65 DNL noise contour. Disapproved with respect to the acquisition of other property and other measures associated with compatible uses (i.e., industrial property within the 65 DNL contour). Local governments retain the right to acquire compatible property outside of the Part 150 program	Pgs. VII–8 to VII–11, Exhibit 15, Map C, and Table 9.

These determinations are set forth in detail in a Record of Approval endorsed by the Administrator on October 14, 1994. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the administrative offices of the Sanford Airport Authority.

Issued in Orlando, Florida on November 9, 1994.

Charles E. Blair,

Manager, Orlando Airports District Office.

[FR Doc. 94–28920 Filed 11–22–94; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review.

November 8, 1994.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the

submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

U.S. Customs Service (CUS)

OMB Number: 1515–0184
Form Number: CF 349
Type of Review: Extension
Title: Exemption from Harbor Maintenance Fee
Description: This information collection is required to carry out the exemption from payment of the Harbor Maintenance Fee. The affected non-profit organizations or cooperatives must provide certain documents, such as IRS Certificate of non-profit status, to prove that they are entitled to the exemption from the fee.
Respondents: Non-profit institutions
Estimated Number of Respondents/ Recordkeepers: 200
Estimated Burden Hours Per Respondent/Recordkeeper: 26 minutes
Frequency of Response: Annually
Estimated Total Reporting/ Recordkeeping Burden: 402 hours
Clearance Officer: Laverne Williams, (202) 927–0229, U.S. Customs Service, Paperwork Management Branch, Room 6316, 1301 Constitution Avenue NW., Washington, DC 20229
OMB Reviewer: Milo Sunderhauf, (202) 395–7340, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 94–28932 Filed 11–22–94; 8:45 am]

BILLING CODE 4820–02–M

Public Information Collection Requirements Submitted to OMB for Review

November 17, 1994.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

U.S. Customs Service (CUS)

OMB Number: 1515–0013
Form Number: CF 3171
Type of Review: Extension
Title: Application-Permit-Special License-Unlading-Lading-Overtime Services
Description: This is an application permit and special license for unlading of passengers, cargo, and baggage from a vessel arriving from any port or place outside the Customs Territory of the United States, or the lading of cargo, baggage or other articles destined to a port or place outside the Customs territory of the United States. It is also an application for overtime or clearance of a vessel.
Respondents: Businesses or other for-profit
Estimated Number of Respondents: 1,500
Estimated Burden Hours Per Respondent: 6 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 39,900 hours
Clearance Officer: Laverne Williams, (202) 927–0229, U.S. Customs Service, Paperwork Management Branch, Room 6316, 1301 Constitution Avenue NW., Washington, DC 20229,
OMB Reviewer: Milo Sunderhauf, (202) 395–7340, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 94–28933 Filed 11–22–94; 8:45 am]

BILLING CODE 4820–02–M

Fiscal Service

1995 Fee Schedule for the Transfer of U.S. Treasury Book-Entry Securities Held at Federal Reserve Banks

AGENCY: Bureau of the Public Debt, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury is announcing the schedule of fees to be charged in 1995 on the transfer of book-entry Treasury securities between depository institution accounts maintained at Federal Reserve Banks and Branches.

EFFECTIVE DATE: January 1, 1995.

FOR FURTHER INFORMATION CONTACT: Carl M. Locken, Jr., Assistant Commissioner (Financing), Bureau of the Public Debt, Room 534, E St. Building, Washington, D.C. 20239–0001, telephone (202) 219–3350.

Diane M. Polowczuk, Government Securities Specialist, Bureau of the Public Debt, Room 534, E St. Building, Washington, D.C. 20239–0001, telephone (202) 219–3350.

SUPPLEMENTARY INFORMATION: On October 1, 1985, the Department of the Treasury established a fee schedule for the transfer of Treasury book-entry securities between one book-entry subaccount to another book-entry subaccount of the same depository institution, and between the subaccounts of one depository institution and the subaccounts of another depository institution that maintain their accounts at Federal Reserve Banks and Branches.

Based on the latest review of book-entry costs and volumes, the Treasury has decided that the fees for securities transfers in 1995 should remain unchanged from the levels currently in effect.

The fees described in this notice apply only to the transfer of Treasury book-entry securities. The Federal Reserve System assesses the fees to recover the costs associated with the processing of the funds component of Treasury book-entry transfer messages, as well as the costs of providing book-entry services for Government agencies. Information concerning book-entry transfers of government agency securities, which are priced by the Federal Reserve System, is set out in a separate notice published by the Board of Governors of the Federal Reserve System.

The following is the Treasury fee schedule that will be effective January 1, 1995, for the Treasury book-entry transfer service:

1995 FEE SCHEDULE

	Cost per transfer
On-line transfers originated	$1.65
On-line reversal transfers received	1.65
Off-line transfers originated	9.40
Off-line transfers received	9.40
Off-line reversal transfers received	9.40

Dated: November 8, 1994.

Gerald Murphy,

Fiscal Assistant Secretary.

[FR Doc. 94–28873 Filed 11–22–94; 8:45 am]

BILLING CODE 4810–35–P

Sunshine Act Meetings

Federal Register
Vol. 59, No. 225
Wednesday, November 23, 1994

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 11:00 a.m., Monday, November 28, 1994.
PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551
STATUS: Closed.
MATTERS TO BE CONSIDERED:

1. Proposed acquisition of computer equipment within the Federal Reserve System.
2. Federal Reserve Bank and Branch director appointments.
3. Proposals regarding fees for directors of Federal Reserve Banks.
4. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
5. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: November 18, 1994.
Jennifer J. Johnson,
Deputy Secretary of the Board.
[FR Doc. 94–28966 Filed 11–18–94; 4:33 pm]
BILLING CODE 6210–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Board of Directors Meeting

TIME AND DATE: Tuesday, December 6, 1994, 1:00 p.m. (Open Portion), 1:30 p.m. (Closed Portion).
PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue, N.W., Washington, D.C.
STATUS: Meeting OPEN to the Public from 1:00 p.m. to 1:30 p.m. Closed portion will commence at 1:30 p.m. (approx.)
MATTERS TO BE CONSIDERED:

1. President's Report.
2. Approval of 09/27/94 Minutes (Open Portion).
3. Meeting schedule through September 1995.

FURTHER MATTERS TO BE CONSIDERED: (Closed to the Public 1:30 p.m.)

1. Finance Project in the NIS.
2. Insurance Project in Peru.
3. Insurance and Finance Project in Colombia.
4. Finance Project in Indonesia.
5. Pending Major Projects.
6. Approval of the 09/27/94 Minutes (Closed Portion).

CONTACT PERSON FOR INFORMATION: Information on the meeting may be obtained from Jane Chalmers at (202) 336–8421.

Dated: November 21, 1994.
Jane H. Chalmers,
Deputy General Counsel.
[FR Doc. 94–29112 Filed 11–21–94; 3:45 pm]
BILLING CODE 3210–01–M

U.S. RAILROAD RETIREMENT BOARD

Notice of Public Meeting

Notice is hereby given that the Railroad Retirement Board will hold a meeting on November 29, 1994, 9:00 a.m., at the Board's meeting room on the 8th floor of its headquarters building, 844 North Rush Street, Chicago, Illinois 60611. The agenda for this meeting follows:

(1) Labor-Management Partnership.

The entire meeting will be open to the public. The person to contact for more information is Beatrice Ezerski, Secretary to the Board, Phone No. 312–751–4920.

Dated: November 18, 1994.
Beatrice Ezerski,
Secretary to the Board.
[FR Doc. 94–29051 Filed 11–21–94; 11:43 am]
BILLING CODE 7905–01–M

federal register

Wednesday
November 23, 1994

Part II

Environmental Protection Agency

Atrazine, Simazine and Cyanazine; Notice of Initiation of Special Review

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000-60; FRL-4919-5]

Atrazine, Simazine and Cyanazine; Notice of Initiation of Special Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Initiation of Special Review.

SUMMARY: This notice announces that EPA is initiating a Special Review on pesticide products containing the herbicides atrazine, simazine and cyanazine. Atrazine [2-chloro-4-(ethylamino)-6-(isopropylamino)-*s*-triazine], simazine [2-chloro-4,6-bis(ethylamino)-*s*-triazine] and cyanazine [2-((4-chloro-6-(ethylamino)-*s*-triazine-2-yl)amino)-2-methylpropionitrile] will be collectively referred to hereafter in this Notice as the triazines. The triazines are widely used herbicides that control many broadleaf weeds and some grasses. All three are used on corn and may be alternatives for each other in some situations. Other uses include citrus, nut orchards (simazine), sugarcane and sorghum (atrazine) and cotton (cyanazine). Based on laboratory animal data, EPA has concluded that these three triazine compounds are possible human carcinogens and has determined that exposure to the triazines in the diet (food and drinking water) may pose risks of concern. EPA has also determined that exposure to these triazines may pose risks of concern to applicators and mixer/loaders who use products containing one or more of these chemicals and to the public who may use home lawncare products containing atrazine. Accordingly, the Agency has concluded that products containing atrazine, simazine and cyanazine meet or exceed the criteria for initiation of Special Review set forth in 40 CFR 154.7(a)(2) and that a Special Review of these products is appropriate to determine whether additional regulatory actions are required.

The Agency is concerned about the potential ecological impacts of ground and surface water contamination resulting from the use of products containing the triazines. Such contamination may have the potential to cause adverse effects to aquatic organisms, terrestrial plants and their ecosystems. The Agency is not including ecological effects as a trigger in this Special Review at this time. This does not preclude the Agency from incorporating ecological effects in this Special Review in the future should the consideration of additional information indicate that a review would be appropriate.

DATES: Comments, data and information to support or rebut the presumptions in this Notice and other relevant information must be received on or before March 23, 1995.

ADDRESSES: Submit three copies of written comments bearing the document number ["OPP-30000-60"], by mail to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. Telephone: 703-305-5805.

Comments and data may also be submitted electronically by any of three different mechanisms: by sending electronic mail (e-mail) to: Docket-OPPTS@epamail.epa.gov; by sending a "Subscribe" message to listserver@unixmail.rtpnc.epa.gov and once subscribed, send your comments to OPP-30000-60; or through the EPA Electronic Bulletin Board by dialing 202-488-3671, enter selection "DMAIL," user name "BB—USER" or 919-541-4642, enter selection "MAIL," user name "BB—USER." Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form should be identified by the docket number OPP-30000-60. Electronic comments on this Notice, but not the complete record,may be viewed or new comments filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit XIII. of this notice.

Information submitted in any comment concerning this Notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public docket. Information not claimed as confidential or not clearly labeled as containing CBI will be placed in the public file and will be disclosed publicly by EPA without further notice to the submitter. All non-CBI written comments will be available for inspection in Room 1132 at the Virginia address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. No CBI should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph E. Bailey, Review Manager, Special Review and Reregistration Division (7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Special Review Branch, 3rd Floor, Crystal Station, 2800 Jefferson Davis Highway, Arlington, VA. Telephone: 703-308-8173. For a copy of documents in the public docket, to request information concerning the Special Review, or to request indices to the Special Review public docket, contact the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Telephone: 703-305-5805.

SUPPLEMENTARY INFORMATION: This Notice describes the Special Review process and the basis for the Agency's decision to initiate this Special Review. The Notice also requests public comment on the triazines including information on their toxicity, possible human and environmental exposure and risks, the benefits of current use, and the risks and benefits of potential chemical and non-chemical alternatives to the triazines. Regarding the benefits of the triazines and their alternatives, the Agency is especially interested in information on use patterns and farming practices that are likely to result in reduced pesticide use and to promote solutions to weed control compatible with the Agency's Sustainable Agriculture and Integrated Pest Management goals. Procedures for submission of public comments to the Agency are described in Unit XIII of this Notice.

This Notice is organized into 15 Units. Unit I describes the Special Review process, legal requirements for the registration of pesticides, and a summary of the Agency's rationale for initiating this Special Review of atrazine, simazine and cyanazine. Unit II summarizes the registration and reregistration history of the triazines as well as interim risk reduction measures that have been implemented. Unit III describes the results of animal studies submitted to the Agency to support continued registration of the triazine herbicides including discussions regarding the toxic effects of the triazines. Agency comments relative to registrants' responses to the preliminary notification to initiate this Special Review for human carcinogenic effects are also discussed in Unit III. Dietary exposure to the triazine herbicides

through food is presented in Unit IV. This unit discusses the measurement of dietary residues of concern and estimation of exposure. Unit V presents the Agency's dietary risk assessment. Unit VI discusses the exposure to triazine herbicides through contaminated drinking water and compares safe drinking water standards to ground and surface water monitoring and detections. The environmental fate of the triazines is also discussed in this unit. Unit VII discusses the risk estimates from exposure to triazine-contaminated drinking water and the registrants' responses to the preliminary notification to initiate Special Review for such risks. Unit VIII discusses triazine exposure and risk estimates from non-dietary sources. Unit IX provides estimations of additive cancer risks from several exposure pathways and chemicals. Ecological exposure and effects of the triazine herbicides are presented in Unit X. This unit discusses ecosystem effects, the effects of triazines on non-target plants and animals and the Agency's comments relative to the registrants' responses to the preliminary notification to initiate Special Review for these concerns. Unit XI presents a use profile of the triazine herbicides and requests information on sustainable agriculture/IPM and reduced pesticide use. Unit XII discusses the requirement for registrants to submit information about unreasonable adverse effects associated with pesticide use and Unit XIII invites interested parties to comment on this Notice. Unit XIV summarizes materials available in the public docket for the triazines and Unit XV lists the references used in preparing this Notice.

I. Background

A. Special Review Process

The Special Review process provides a mechanism to permit public participation in EPA's deliberations prior to issuance of any Notice of Final Determination describing the regulatory action which the Administrator has selected. The Special Review process is described in 40 CFR part 154, published in the **Federal Register** of November 27, 1985 (50 FR 49015). During the Special Review process the Agency: (1) announces and describes the basis for the Agency's finding that use of the pesticide meets one or more of the risk criteria set forth in 40 CFR 154.7; (2) establishes a public docket; (3) solicits comments from the public regarding whether the use of a pesticide product as currently registered or as it is proposed to be registered satisfies any of the risk criteria for initiation of Special Review set forth at 40 CFR 154.7, or whether any risks posed by the use or proposed use of the product that satisfy risk criteria at 40 CFR 154.7 are unreasonable, taking into account the economic, social, and environmental costs and benefits of the use of the product; and what regulatory action, if any, the Agency should take with respect to the use of the product; (4) solicits comment from the Secretary of Agriculture and the Scientific Advisory Panel if the Administrator proposes to cancel, deny, or change the classification of the registration of a pesticide product which is the subject of Special Review, or to hold a hearing under FIFRA section 6(b)(2) on whether to take any of those actions; (5) reviews and responds to all significant comments submitted in a timely manner; and (6) makes a final regulatory decision based on the balancing of risks and benefits associated with the pesticide's use.

Issuance of this Notice means that potential adverse effects that may be associated with the use of pesticide products containing atrazine, simazine or cyanazine have been identified and will be examined further to determine their extent and whether, when considered together with the benefits of these pesticides, such risks are unreasonable.

B. Legal Requirements

A pesticide product may be sold in the United States only if it is registered or exempt from registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (7 U.S.C. 136 et seq.). Before a product can be registered it must be shown that it can be used without "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide" [FIFRA section 2(bb)]. The burden of proving that a pesticide meets this standard for registration is, at all times, on the proponent of initial or continued registration. If at any time the Agency determines that a pesticide no longer meets this standard, the Administrator may cancel this registration under section 6 of FIFRA.

C. Preliminary Notification

Prior to the public announcement of initiation of a Special Review, pursuant to 40 CFR 154.21, registrants of the affected pesticide are given preliminary notification that the Agency is considering initiating a Special Review. Registrants are given 30 days to respond in writing to dispute the validity of the Agency's conclusions or to present any information in response to the Agency's risk concerns included in this notification.

EPA issued preliminary notifications of its intention to initiate a Special Review of atrazine, simazine and cyanazine to all registrants of these chemicals on February 8, 1994 (Refs. 1, 2, and 3). This notification included a brief statement of the Agency's concerns. The data and preliminary risk assessments triggering this Special Review are described in detail in subsequent units of this notice. A discussion of registrants' responses to the preliminary notifications is also included.

D. Determination to Initiate Special Review

The Agency has determined that the estimated risks to humans posed by atrazine, simazine and cyanazine warrant the initiation of a Special Review of each of these chemicals. The Agency has also determined that a combined Special Review of atrazine, simazine and cyanazine is more appropriate than examining each individually. This determination is based on the following considerations: all three (1) are structurally related chemicals, (2) induce mammary tumors when fed to rats and are classified as Group C, possible human carcinogens, (3) degrade or metabolize to similar degradates/metabolites, (4) are generally similar in terms of environmental fate including relative persistence, leachability, run-off potential and possibly atmospheric transport, (5) are similar in toxicity to aquatic organisms and terrestrial plants, and (6) may serve as alternatives to each other for some situations.

The Agency is concerned about the potential excess individual lifetime cancer risks resulting from dietary exposure to triazine-treated food/feed commodities as well as the potential cancer risks to persons mixing, loading and applying products containing the triazine herbicides, including residential exposure to persons using lawn care products containing atrazine. EPA is also concerned about the potential risks resulting from the consumption of drinking water (from ground and surface water sources) contaminated with triazines and their degradates (metabolites), in particular the chloro degradates. Furthermore, the Agency is concerned about the additive impacts that may occur to persons exposed to more than one triazine, or through more than one exposure pathway.

While the Agency is also concerned about the potential harmful impacts on

nontarget organisms (aquatic organisms, terrestrial plants) and their ecosystems that may result from continued use of triazine herbicides, it is not, at this time, including ecological effects in this Special Review. The Agency's concerns regarding ecological effects of the triazines are discussed more fully in Unit X of this notice.

II. Regulatory History of the Triazine Herbicides

This unit summarizes the registration and reregistration history of the triazines including the Data Call-In Notices (DCIs) issued for atrazine, simazine and cyanazine and interim risk reduction measures imposed during the course of the Agency's review of the triazines.

A. Atrazine

Ciba Plant Protection (formerly Ciba-Geigy Corporation) first registered atrazine in 1959 and remains the lead registrant of the technical compound from which most end-use products are formulated. Ciba is responsible for generating data to support the continued registration of products containing this chemical. Other atrazine technical registrants are Oxon Italia S.P.A. and Drexel Chemical Company. Altogether, there are currently 36 registrants with a total of 98 registrations for products containing atrazine.

In 1983, EPA issued a Registration Standard for atrazine. The Standard noted the Agency's concern about the dietary carcinogenic risk from ground and surface water contamination. In 1988, EPA issued a preliminary notification of the Agency's intention to initiate Special Review to atrazine registrants based on concerns regarding the carcinogenic potential of atrazine and possible risks resulting from exposure to atrazine in the diet from treated food and from contaminated drinking water. Another concern surrounded the potential carcinogenic risks to workers exposed while mixing, loading and applying products containing this chemical (Ref. 4). A Data Call-In Notice (DCI) issued in November 1988 required submission of information regarding results of ground and surface water monitoring and use and usage data.

In 1989, EPA notified registrants of an additional concern based on the results of a laboratory study showing atrazine cardiotoxicity (heart damage) in dogs (Ref. 5). The Agency issued a DCI requiring an additional study in order to further explore the findings regarding cardiac effects. Since that time, the Agency's concerns regarding cardiotoxicity have been resolved and are discussed in Unit VIII of this Notice.

In 1990, the Agency accepted proposed voluntary risk reduction measures from Ciba which included label amendments that reduced application rates of atrazine and classified the chemical as a "Restricted Use Pesticide" based on ground water concerns for agricultural uses. (Commercial, home and garden, and turf/lawn care uses were not restricted.) These risk reduction measures partially addressed EPA's ground water concerns largely by implementing measures to reduce the potential for point-source contamination.

In September 1990 as part of the reregistration requirements for atrazine, the Agency issued a comprehensive DCI listing all remaining atrazine data requirements. In April 1992, EPA accepted additional voluntary proposals by atrazine registrants to further restrict atrazine use including protective measures to partially address the Agency's concerns regarding atrazine contamination of surface water. These restrictions included reducing maximum application rates, deleting some uses and establishing set-backs and buffer zones from surface water for mixing, loading and application. The registrant also undertook research studies to help determine the effects of set-backs on water quality and to further determine atrazine contamination of lakes and reservoirs.

B. Simazine

Ciba first registered simazine in 1957 and currently produces approximately 80 to 90 percent of the technical product. There are two other technical registrants: Oxon Italia and Drexel. There are a total of 16 registrants with 38 registered products containing simazine.

The Registration Standard for simazine, issued in March 1984, expressed the Agency's concern about simazine's potential for ground water contamination and classified it as a "Restricted Use Pesticide" based on this concern. In 1985, the Agency withdrew simazine's "Restricted Use" classification and imposed both ground water advisory and aquatic invertebrate toxicity statements on the label.

In August 1989, EPA issued a DCI requiring ground and surface water monitoring information and simazine use data. EPA issued a comprehensive DCI in September 1991 requiring data for reregistration including toxicological and residue data. In response to the DCI, Ciba elected not to support the aquatic uses of simazine and subsequently voluntarily cancelled these uses on all of its registered products (Ref. 6).

In August 1993, EPA conducted a risk assessment for simazine algaecide products used in swimming pools, hot tubs and whirlpools, and concluded that water treated with simazine algaecides posed unacceptable cancer and non-cancer health risks to children and adults. After completing the risk assessment, the Agency notified the registrants of its concerns. Most registrants requested voluntarily the cancellation of their end-use products registered for such uses with no provisions for use of existing stocks. The cancellation order for these products was effective April 15, 1994 (Ref. 7). The remaining products for which voluntary cancellation was not requested were cancelled through a Notice of Intent to Cancel published in the **Federal Register** on July 7, 1994 (Ref. 8). When the final cancellation order became effective, further sale, distribution and use of existing stocks of products for these uses was prohibited.

C. Cyanazine

In 1971, Shell Chemical Company first registered cyanazine under the trade name Bladex. DuPont Agricultural Products and Ciba Plant Protection are now the only registrants. DuPont, having the only technical registration, takes the lead in generating data to support continuing registration.

The cyanazine Registration Standard, issued by EPA in December 1984, classified this chemical as a "Restricted Use Pesticide" based on its detection in ground and surface water. Label statements regarding developmental toxicity concerns and ground and surface water detections were added to cyanazine labels but did not explicitly link the restricted use classification to these concerns. A Special Review of cyanazine was initiated in April 1985 based on studies showing developmental toxicity in two species after oral administration of the chemical. Estimated risks to mixer/loaders and applicators were of concern. Dermal developmental toxicity studies were submitted that led to a refinement of the risk assessment and a determination that if additional risk reduction measures were adopted, occupational risks would be partially mitigated. The Special Review was concluded in 1988 by requiring the use of protective gloves, chemical-resistant aprons for mixer/loaders and closed mixing/loading systems for aerial application and chemigation (application of pesticides through irrigation). The Agency also required revised label language specifically

linking cyanazine's "Restricted Use" status to its developmental effects. Because of the detections of cyanazine in ground water, the Agency determined that the ground water advisory statement was appropriate for cyanazine labels.

In January 1991, EPA issued a DCI requiring information on the results of cyanazine ground water monitoring data to upgrade a monitoring study for cyanazine and one metabolite.

In April 1992, as part of the reregistration of cyanazine, EPA issued a DCI requiring residue chemistry, environmental fate and ecological effects data. For Special Review purposes, the DCI also required the registrants to submit all existing data on usage, pest management, comparative product performance and pest resistance data. These data were received in October 1992.

In 1993, the Agency approved label use restrictions proposed by the cyanazine registrants to partially address the Agency's ground and surface water concerns. Label amendments include reduced maximum application rates and surface water setbacks, similar to those previously approved for atrazine in 1992.

III. Toxicity of Atrazine, Simazine and Cyanazine

In laboratory animal studies, all three triazines induce mammary tumors in one strain of one species (the female Sprague-Dawley rat) and, based on a weight-of-evidence approach, all three chemicals are classified by EPA as Group C (possible human) quantified carcinogens. This unit describes the results of required and voluntary toxicological laboratory data and other studies submitted in support of the continued registration of the triazine herbicides, the Agency's cancer classification of the triazines, findings by the EPA Cancer Peer Reviews and the FIFRA Scientific Advisory Panel (SAP), and the registrants' position regarding the Agency's cancer risk assessment.

A. Atrazine

1. Carcinogenicity— a. *Rat study.* Atrazine was administered in the daily diet of Sprague-Dawley rats (50/sex/dose) at doses of 0, 10, 70, 500, or 1,000 ppm for 2 years. An additional 10 rats per sex were placed on control (0 ppm) and high dose (1,000 ppm) diets for 12- and 13-month sacrifices (Ref. 9). Administration of atrazine to female rats was associated with a statistically significant increase in mammary gland fibroadenomas at 1,000 ppm; mammary gland adenocarcinomas [including two carcinosarcomas at the highest dose tested (HDT)] at 70, 500, and 1,000 ppm; and total mammary gland tumor-bearing animals at 1,000 ppm in comparison to control animals. In males, the incidence of testicular interstitial cell tumors was increased at the high dose in comparison to controls. This increase was associated with a significant dose-related trend driven by high dose effect; however, this statistically significant increase was within the historical control range. There was an increase in retinal degeneration and in centrilobular necrosis of the liver in high-dose females and an increase in degeneration of the rectus femoris muscle in high-dose males and females when compared to controls. Based on decreased body weight gain, the Lowest-Observed-Effect Level (LOEL) for chronic toxicity in males and females is 500 ppm and the No-Observed-Effect Level (NOEL) is 70 ppm.

b. *Mouse study.* Atrazine was administered in the daily diet of CD–1 (Charles River Laboratories) mice (60/sex/dose) at 0, 10, 300, 1,500 or 3,000 ppm for 91 weeks (Ref. 10). Administration of atrazine to mice was not associated with any treatment-related changes in the incidence of palpable masses in male or female mice. No statistically significant increases in incidence were found for the following types of neoplasms: mammary adenocarcinomas, adrenal adenomas, pulmonary adenomas and malignant lymphomas. The LOEL and NOEL are determined to be 1,500 ppm and 300 ppm, respectively, based upon decreases in mean body weight gain at 91 weeks.

c. *Mutagenicity.* Mutagenicity studies evaluate the potential for a chemical to promote genetic alterations in cells. The registrant has submitted five mutagenicity studies that meet EPA guideline requirements using atrazine. The results of these studies are negative. The registrant also performed an unscheduled DNA synthesis (UDS) assay to satisfy remaining reregistration requirements. The Agency's review of this study concluded that atrazine did not induce UDS in primary rat hepatocytes.

d. *Cancer classification.* There have been three Office of Pesticide Programs (OPP) Carcinogenicity Peer Reviews to evaluate atrazine's carcinogenic potential. Two reviews were conducted prior to submission of this chemical to the SAP for review, and one subsequent to the SAP review.

The first Carcinogenicity Peer Review Committee met in September 1987 and concluded that the available data provided limited evidence for the carcinogenicity of atrazine in rats. The Committee tentatively classified atrazine as a Group C (possible human) carcinogen based on an increased incidence of mammary tumors in female Sprague-Dawley rats. While awaiting an acceptable mouse carcinogenicity study, the Committee concluded that a quantitative risk assessment should be performed due to the induction of mammary gland tumors and possible decreased latency for their appearance, and the structural similarity to other then-registered triazine herbicides classified as Group C carcinogens (Ref. 11).

A second Carcinogenicity Peer Review was held in June 1988 and confirmed the earlier findings. This review included an evaluation of the mouse carcinogenicity study, in which no compound-related carcinogenic effects were observed (Ref. 12).

In September 1988, the OPP Carcinogenicity Peer Review Committee presented its position to the SAP. The SAP agreed with the Group C classification but not with a Q_1^* approach to quantify risks (Ref. 13). The SAP stated that the variability of the endpoint and its potential for secondary hormonal influence, as suggested by endocrine imbalance at high, but not low, doses indicated that the proposed quantitative risk assessment was inappropriate for this chemical.

Shortly after the SAP presentation, a third Peer Review of atrazine was held and, upon reevaluation of the available data and the SAP comments, the OPP Carcinogenicity Peer Review Committee determined that the data were not appropriate for quantitative risk assessment and that the registrant should continue to generate data to support a hormonal mechanism of carcinogenicity (Ref. 13). In November 1988, the Committee reevaluated their decision from the third Peer Review and reverted to their original conclusion that a quantitative risk assessment for atrazine was appropriate (Ref. 14). The Committee based its decision to quantify the risk on a weight-of-evidence approach including the following considerations: (a) tumors in one species (rat) and one sex (female); (b) an increase in primarily malignant type tumors (adenocarcinomas) as contrasted with benign types; (c) both adenocarcinomas and the number of mammary tumor bearing animals were statistically increased at doses of 70, 500 and 1,000 ppm; (d) a possible treatment-related increase in rate of tumor appearance; and (e) the structure activity relationship between atrazine and other compounds of known carcinogenic potential. The Committee concluded that there were still

insufficient data to support a hormonal mechanism theory.

e. *Determination of the Q_1**. The Agency uses the linearized multi-stage model to extrapolate from effects seen at high doses in laboratory studies to predict tumor response at low doses. This model is based on the biological theory that a single exposure to a carcinogen can initiate an irreversible series of transformations in a single cell that will eventually lead to tumor formation. In addition, the linearized multi-stage model assumes that the probability of each transformation is linearly related to the degree of exposure (i.e., a threshold does not exist for carcinogenicity).

Using this model, the cancer potency estimate in human equivalents (Q_1*) for atrazine is 2.2×10^{-1} $(mg/kg/day)^{-1}$, which represents the 95 percent upper confidence limit (UCL) of tumor induction likely to occur from a unit dose (Ref. 15).

2. *Cardiotoxicity.* In 1987, atrazine registrants submitted to the Agency the results of a 1–year chronic dog feeding study in which the animals were dosed at 0, 0.5, 5 or 34 mg/kg/day. The study authors concluded that treatment-related effects, EKG alterations and cardiac lesions, were observed only at the highest dose tested. The Agency's review of the study resulted in the conclusion that treatment-related effects were seen at the mid-dose level as well as the high-dose level. Consequently, the Agency established a NOEL for cardiotoxicity at 0.5 mg/kg/day. The registrant submitted additional individual animal information on the chronic dog study and after reviewing these data, the Agency agreed with the registrants that treatment-related effects were, in fact, seen only at the high-dose level. Accordingly, the NOEL was increased from 0.5 to 5.0 mg/kg/day based on EKG alterations and cardiac lesions (Ref. 16).

B. Simazine

1. *Carcinogenicity— a. Rat study.* Simazine technical was administered in the diet to groups of 50 male and female Sprague-Dawley (S-D) rats at 0 (control), 10, 100 or 1,000 ppm for 2 years. Additional groups (30-40/sex/dose) were also treated (Ref. 17). The statistically significant effects in the test animals are as follows:

(1) *Female S-D rats.* (a) There was a statistically significant increase in mortality in female rats.

(b) There was a statistically significant dose-related trend for mammary gland carcinomas and combined adenomas/fibromas/carcinomas; however, when the shortened life-span of the female rats was included in the statistical evaluation, the incidences of carcinoma alone at both the 100 and 1,000 ppm [Highest Dose Tested (HDT)] dosage groups were statistically significantly increased as well. The upper limit of the historical control incidence reported for mammary carcinoma was exceeded at 100 ppm, and greatly exceeded at 1,000 ppm (HDT). The incidence of cystic glandular hyperplasia in the mammary gland was statistically significantly increased at the HDT, which correlates with the observed high tumor incidence at that dose.

(c) There was a statistically significant dose-related trend for kidney tubule adenomas; however, as in the case of the male rats, tumors occurred only at the HDT and the incidence was not statistically significant by pairwise comparison with that in the concurrent control group. The incidence for adenomas and/or carcinomas reported for historical controls was zero in all seven available studies.

(d) There were also statistically significant dose-related trends for adenomas, carcinomas and combined adenoma/carcinomas of the pituitary gland. The incidence of pituitary gland carcinoma at 1,000 ppm (HDT) only slightly exceeded the upper bound of the historical control range; it greatly exceeded the incidence reported in six out of the seven available studies.

(2) *Male S-D rats.* (a) In male rats, there was a statistically significant decrease in mortality when compared to females treated with the same dose.

(b) The incidence of liver tumors was significantly increased for carcinoma and for combined adenoma/carcinoma at 100 ppm and 1,000 ppm (HDT), respectively; however, these results fell within the range reported for historical controls.

(c) There was also a statistically significant dose-related trend for kidney tubule carcinomas, and for combined adenomas/carcinomas; however, tumors occurred only at the HDT and neither incidence was statistically significant by pairwise comparison with that in the concurrent control.

b. *Mouse study.* There is no evidence that simazine induces cancer in the mouse (Ref. 18).

c. *Mutagenicity.* The Agency has received one acceptable mutagenicity study, the *Salmonella* assay, which was negative (Ref. 19). Published information reports some possibly positive mutagenicity and genotoxicity studies.

d. *Cancer classification.* The OPP Carcinogenicity Peer Review for simazine, held in May 1989, concluded that simazine is a Group C carcinogen and that carcinogenic risks should be quantified (Ref. 20). The Committee considered the following to be of importance in its weight-of-the-evidence determination: similar structure activity relationship to other *s*-triazines, particularly atrazine; the same tumor type as atrazine (mammary gland tumors in the rat); malignant tumors in the pituitary gland; negative findings for carcinogenicity in the mouse; and several questionable positive mutagenicity and genotoxicity studies reported in published literature. The Peer Review Committee concluded that there were inadequate data to support a hormonal mechanism theory.

e. *Determination of the Q_1**. Using the same model described earlier for estimating the Q_1* for atrazine, the cancer potency equivalent for simazine, based on malignant mammary tumors in the rat, is estimated at 1.2×10^{-1} $(mg/kg/day)^{-1}$ (Ref. 21). This represents the 95 percent UCL of tumor induction likely to occur from a unit dose.

The SAP review of simazine (September, 1989), while agreeing with the Group C classification, did not recommend the use of a quantitative risk assessment. The SAP noted that certain pesticides may alter endocrine physiology in the rat and influence the incidence of mammary tumors and recommended that the Agency formulate a position on the regulation of chemicals with this mechanism. At a subsequent OPP Peer Review meeting (April, 1990), the Committee evaluated the SAP's recommendation and concluded that it is appropriate to use a low dose extrapolation model (Q_1*) to quantify the carcinogenic risks of exposure to simazine unless the registrant provides data showing a hormonally mediated mechanism of action for the mammary tumor development (Ref. 22). Data have not been received that support a hormonal mechanism.

C. Cyanazine

1. *Carcinogenicity—* a. *Rat study.* In a combined chronic toxicity/carcinogenicity study with cyanazine in Sprague-Dawley rats, groups of 52 males and 52 females were fed cyanazine technical at concentrations of 0, 1, 5, 25, or 50 ppm in the diet for 2 years (Ref. 23). Additionally, 10 animals per sex per group were used as a satellite group for interim sacrifice at 12 months. The highest dose tested was considered to be adequate for carcinogenicity testing based upon decreased body weight gain of about 14 percent in both males and females in the first 3 months of the study. However, the Agency concluded

that the animals could probably have tolerated a higher dose.

Findings from this study include a statistically significant increase in malignant mammary gland tumors (adenocarcinoma and carcinosarcoma) in females of the 25 and 50 ppm groups, with a statistically significant positive trend. The incidences of malignant tumors were outside the historical control range of 10.1 to 22.7 percent with an average of 17.9 percent.

Generally, there were no non-neoplastic lesions that could be attributed to treatment with cyanazine, due to a lack of historical control data. However, three lesions were observed that have not been reported with other triazine herbicides. These lesions were: (i) granulocytic hyperplasia of bone marrow in males; (ii) extramedullary hematopoiesis of the spleen in males; and (iii) demyelination of the sciatic nerve in females.

b. *Mouse study.* Findings show that dietary administration of cyanazine did not alter the spontaneous tumor profile in the CD-1 mouse (Ref. 24).

c. *Mutagenicity.* There is some evidence that cyanazine has mutagenic activity. Of the submitted studies, cyanazine has been found to be positive in a mouse lymphoma assay (dose-responsive in repeat assays) and a UDS assay (Ref. 25). Results of another UDS assay in rat spermatocytes following an *in vivo* exposure were negative (Ref. 26).

d. *Cancer classification.* In March 1991, the OPP Carcinogenicity Peer Review Committee evaluated the weight-of-the-evidence on cyanazine, with particular emphasis on its carcinogenic potential. The Peer Review Committee concluded that cyanazine should be classified as a Group C, possible human carcinogen and recommended quantification of human risk using a low dose extrapolation model (Q_1*) (Ref. 24).

In addition to the mammary gland tumors observed in the female Sprague-Dawley rat, the weight-of-the-evidence for the carcinogenic potential of cyanazine includes the evidence that cyanazine is structurally related to the other chloro-*s*-triazines which also induce mammary gland cancer in experimental animals. However, cyanazine differs structurally from other triazines in that the molecule has a cyano (nitrile) functional group in the alkyl substituent of one the amino groups. The presence of this highly reactive cyano group favors a different metabolic breakdown pathway indirectly indicating that cyanazine can generate a more electrophilic arylating agent than other chloro-*s*-triazines, and is consistent with the finding that cyanazine has a more positive genotoxicity profile than the other chloro-*s*-triazines.

e. *Determination of the Q_1*.* Using the same model described earlier for estimating the Q_1*s for atrazine and simazine, the cancer potency equivalent for cyanazine, based on development of adenocarcinomas and carcinosarcomas in female rats, was estimated at 8.4×10^{-1} $(mg/kg/day)^{-1}$. The Agency's Carcinogen Risk Assessment Verification Endeavor workgroup has increased the Q_1* to 1.0×10^{0} $(mg/kg/day)^{-1}$ based on a revised oral slope factor. This represents the 95 percent UCL of tumor induction likely to occur from a unit dose (Ref. 27). The cancer classification for this chemical has not been presented to the SAP for review.

D. Epidemiology Data

It is often difficult to establish a link between cause and effect with human epidemiological data. Such data exist for the triazines but, as with any data of this type, it is difficult to clearly attribute findings to triazine exposure. However, the Agency's review of two Italian field worker studies indicates a possible association between ovarian cancer and exposure to atrazine and simazine (Ref. 28). In another study, preliminary results show a correlation between atrazine concentrations in local areas surrounding Rathbun Lake, Iowa, and birth defects including heart, urogenital tract and limb reductions (Ref. 29). Also, the Agency has reviewed published summaries of several cancer epidemiology studies concerning triazine use in the Midwest; these studies provide some evidence of an association between non-Hodgkin's lymphoma and triazine exposure, but other explanations or confounding factors could account for the association (Ref. 30).

Breast cancer in humans and triazine herbicides. Data from carcinogenicity studies discussed earlier show that there is an association between the administration of the triazines to Sprague-Dawley rats and an increase in the incidence of mammary tumors in female rats. The Agency does not have data or substantial epidemiological evidence to definitively link the triazine pesticides to breast cancer in humans; however, reports have been published that attempt to associate breast cancer in humans to exposure to triazines (Refs. 31 and 32). The relevance of the mechanism for mammary tumorigenesis in rats to that in humans has not been documented and species differences have been found to exist (i.e., cells of origin, degree of endocrine responsiveness and metastatic potential). The mechanisms for tumor formation in Sprague-Dawley rats and the implications for causing breast cancer in humans are currently being investigated. Until there are data to definitively refute or support the possibility for certain triazines to be human mammary carcinogens, the Agency must regulate these compounds based on the available animal data and the assumption that the chemicals' potential to cause cancer in animals may indicate the possibility that they can cause cancer in humans.

E. Registrants' Response to Preliminary Notification Concerning Carcinogenic Risks and Agency Comments

Responses to the Agency's preliminary notification were received from Ciba for atrazine and simazine, and from DuPont for cyanazine. Both registrants responded with regard to the Agency's concern regarding cancer risks associated with exposure to the triazine herbicides. Ciba and DuPont contend that the exact mechanism of the strain-specific mammary gland tumorigenesis in Sprague-Dawley rats has not yet been elucidated, and therefore, the association of cancer risks in animals to human cancer risks should not be drawn. Ciba indicated a willingness in its response to conduct additional research on the strain-specific response to atrazine and requested that the Agency consider additional research before reaching conclusions about the cancer causing potentials of atrazine and simazine. DuPont indicated in its response that research is currently being conducted to determine the mechanism of cyanazine-induced mammary gland tumors; this research is expected to be completed in late 1995. Both registrants requested that the Agency consider this additional information before reaching definitive conclusions about triazine cancer risks.

In response to the above comments received from Ciba and DuPont, the Agency's position is that, as of the publication of this notice, all information available concerning the carcinogenic potential of atrazine, simazine and cyanazine has been considered in the Agency's occupational and dietary risk assessments. The Agency believes that the current method of quantifying cancer risks using the Q_1* is appropriate considering the available data. To date, Dupont has submitted no reports or studies that show the mechanism by which cyanazine induces tumors. Ciba submitted a four-part voluntary hormonal study for atrazine to address the issue of a hormonal threshold mechanism. Because of the similarities between atrazine and

simazine, the registrant contends that conclusions drawn regarding atrazine will also apply to simazine. The Agency has considered the information provided by Ciba that attempts to explain the mechanism of mammary tumorigenesis in rats exposed to atrazine but concludes that the data do not actually explain any such mechanism and therefore are not adequate to support a mechanism of action operating through a hormonal mechanism and/or threshold (Refs. 33, 34, and 35). If the registrants' theory that the mammary tumors seen in laboratory studies of the triazines is, at some future date, proven to be the result of a hormonal imbalance in the rat that occurs only at higher doses, the Agency could choose to quantify the risk using an MOE/RfD or other approach rather than using a Q_1*. However, based on available data, the Q_1* serves as the regulatory endpoint.

Ciba has also hypothesized that the differences in mammary tumor response to atrazine by Sprague-Dawley and Fischer 344 rats can be attributed to differences in endocrinology between the strains. To address the issue of the effects being strain-specific, Ciba submitted a voluntary study comparing the effects of atrazine on Sprague-Dawley and Fischer rats. However, the Agency does not believe that the data provided by Ciba adequately support the theory that reproductive hormonal differences between the two strains accounts for the differences in tumor response (Ref. 33).

An International Life Sciences Institute/Risk Science Institute (ILSI) workgroup is examining the suitability of the Sprague-Dawley rat as a model for mammary tumor formation in humans. If the Agency were to agree with a conclusion that the Sprague-Dawley is not an appropriate model, the weight-of-evidence determination for the triazines would in all likelihood be modified. That is, they may no longer be classified as possible human carcinogens. The ILSI workgroup is expected to issue a background report discussing the state of the science on this issue by the end of 1994.

Ciba has stated that atrazine-induced endocrinologic changes in the female Sprague-Dawley rat are not relevant to mammary tumorigenesis in human females. The Agency acknowledges that not all of the risk factors associated with the etiology of human breast cancer are known; however, the Agency believes that some parallels may exist in terms of the cause of initiation and development of mammary tumors in female rodents and humans. Finally, the Agency does not want to preclude the possibility that the potential for tumorigenesis at other target sites may exist in humans as a result of exposure to the triazines. The Agency will consider and appropriately incorporate into its risk assessments any additional data provided that may better characterize the carcinogenicity of the triazine herbicides during the course of this Special Review.

IV. Triazine Dietary (Food/Feed) Exposure

Human dietary exposure to the triazines can occur from residues remaining in or on treated crops including corn, orchard fruits, nuts and sugarcane. Dietary exposure to the triazines may also occur from consumption of residues in animal commodities including meat, milk, poultry and eggs, that result from animals having been fed triazine-treated crops (including corn, sorghum and sugarcane). This unit describes the Agency's assessment of human dietary exposure to the triazines and the uncertainties associated with that assessment. Triazine dietary risks are summarized in Unit V of this notice. In triazine use areas, human exposure may also occur through contaminated drinking water from ground or surface water sources. A discussion of exposure and risks from triazine-contaminated drinking water is presented in Units VI and VII of this notice.

A. Toxic Residues of Concern

In estimating triazine dietary risks, the Agency assumes that the total toxic residue of concern is the parent triazine compound plus all metabolites with a triazine ring, including among others, all chloro and hydroxy metabolites. When there are insufficient data concerning the toxicity of metabolites, it is the Agency's policy to make the conservative assumption that structurally-related metabolites are as toxic as the parent compound. Therefore, in estimating risks, it is appropriate to consider all of the triazine metabolites measured as well as the parent compounds.

In plants, atrazine and simazine are metabolized to numerous metabolites, no one of which has yet been shown to comprise a large portion of the total terminal residue. Metabolic processes include *N*-dealkylation and conjugation with endogenous plant components, particularly glutathione, and hydroxylation. Most metabolites have been shown to contain the intact triazine ring. In soils, atrazine and simazine are metabolized to dealkylated chloro metabolites and hydroxy analogues of the parent compounds. The dealkylated chloro metabolites tend to be more mobile in soils than the hydroxy parent analogues.

In animals, data have been provided showing the animal metabolism of atrazine, simazine, and corn metabolites of atrazine (animals were fed corn which had been treated with atrazine). Higher tissue residues resulted from feeding atrazine or simazine, and numerous metabolites were identified resulting from *N*-dealkylation and conjugation with glutathione followed by modification of the glutathione moiety. In most cases, no single metabolite accounted for a significant percentage of the total residue. Exceptions to this were milk in which the di-*N*-dealkylated chloro metabolite (G–28273) comprised approximately 30 percent of the total residue for atrazine, and liver in which the cysteine conjugate of G–30033 comprised approximately 25 percent of the total residue. When corn treated with atrazine was fed to animals, much lower residues resulted in tissues indicating less absorption of metabolites than of the parent compounds.

The metabolism of cyanazine in plants is slightly different from that of atrazine and simazine in that a limited number of metabolites (Ref. 9) comprise most of the terminal residue. Cyanazine metabolites result from a combination of ring hydroxylation (displacement of chlorine), deethylation, and oxidation of the cyano group to form amides and acids.

Although the metabolism of cyanazine in animals is not yet adequately understood, preliminary information suggests that some of the same metabolites found in plants are also found in animals.

B. Anticipated Residues

The Agency presently considers the triazine chloro metabolites to possess equivalent potency to the parent compounds with regard to carcinogenicity; however, this assumption is made from studies in which animals were fed parent compound only. Based on its assessment of the structure-activity relationship and potential carcinogenicity of all registered triazine compounds, EPA believes metabolites which have been dechlorinated may be less potent carcinogens than the parent compounds. An interim report on a voluntary hydroxyatrazine carcinogenicity study, which indicated negative findings at the end of 1 year, supports this hypothesis. A second interim report has been received and is currently being reviewed by the Agency. However, in the absence of completed

laboratory studies on the carcinogenicity of the hydroxy metabolites, the Agency has relied on its equivalency policy and has made the assumption that all metabolites containing the triazine ring are equipotent as carcinogens as the parent compound when conducting its risk assessment. If the data in the final report are available in a timely fashion and indicate that the hydroxy metabolites are not carcinogenic, the Agency will then base its dietary exposure and cancer risk assessment for atrazine and simazine on the parent compounds plus those metabolites other than the hydroxy metabolites. As a result, the estimated dietary cancer risks for atrazine and simazine would appear to be reduced compared with current estimates. A decision has not yet been made by the Agency on how the results of the hydroxyatrazine carcinogenicity study will affect which metabolites are included in the risk assessment for cyanazine. The final results of the hydroxyatrazine study are expected in early 1995.

1. *Atrazine and simazine.* For atrazine and simazine, the Agency has based its current dietary risk assessment on both radiolabel studies (both field and greenhouse) and field trials (non-radiolabel studies). Estimated residue levels were determined using radiolabel studies for corn, sorghum and animal commodities. Field trial data were used for all other commodities. Residue estimates from radiolabel studies include residues of all triazine ring containing metabolites. Residue estimates from field trials include either the parent compound only, or the parent compound plus chloro metabolites. The best available data currently indicate that the parent and chloro metabolites comprise only a small portion (less than 5 percent) of the total triazine ring residue in most commodities.

These data introduce uncertainty into the dietary risk assessment for two major reasons. First, when field trial data are used, only a small portion of the total toxic residue is considered in the risk assessment. Because the percentage of parent plus chloro metabolites relative to the total triazine ring residue would be expected to vary somewhat from crop to crop, the percentage of the total estimated risk accounted for by these data is not known, but will always lead to an underestimate of risk when detectable residues are present. Second, no detectable residues were found in many commodities, particularly for simazine. Where there are no detectable residues, the Agency assumes that the residues are 1/2 the analytical method limit of detection (LOD). The actual residues could be far less than 1/2 the LOD leading to an overestimation of the risk or greater than 1/2 the LOD but less than the LOD leading to an underestimate.

Since the registrants have been unable to develop analytical methodology which measures total triazine ring residues in non-radiolabel field trials, radiolabel field studies currently provide the best data to use for risk assessment. New radiolabel field studies for major dietary risk contributors for both atrazine and simazine have been submitted to the Agency and are currently under review. Preliminary reviews of the data do not indicate that currently estimated dietary risks will change significantly.

2. *Cyanazine.* The sources of information for calculating all anticipated residues of cyanazine in crop commodities were residue data from field trials and processing studies and, in some cases, data translated from metabolism studies (Ref. 36).

Cyanazine metabolism studies indicate that regulated metabolites account for greater than 90 percent of the total triazine ring-containing residue. Because a small set of discrete, measurable metabolites make up a large portion of the total triazine ring residue, field radiolabel studies are not necessary for cyanazine. Therefore, the Agency's dietary risk assessment is not expected to change based on submission of additional residue data.

V. Triazine Dietary (Feed/Food) Risk Assessment

A. Dietary Cancer Risks

Dietary (food/feed) cancer risks for the triazines were estimated for the overall U.S. population using the following relationship:

Upper bound estimated carcinogenic risk = Dietary exposure (Anticipated Residue Contribution) x Q_1*.

It should be remembered that the Agency's procedures for quantifying cancer risks actually identifies a range, rather than just a single value. The upper boundary on that range is the risk using the upper 95 percent confidence limit on the toxicology data. The lower boundary on the range is zero. Thus, actual risk to humans may be as low as zero. Toxicological studies and calculation of Q_1*s for atrazine, simazine and cyanazine were described in Unit III of this notice; dietary exposure assumptions were described in Unit IV of this notice.

1. *Atrazine cancer risk estimates.* The dietary risk assessment for atrazine was conducted based on total triazine ring residues for corn, sorghum and animal commodities, and on parent, or parent and chloro metabolite residues for all remaining crops. This analysis resulted in a combined estimated upper bound carcinogenic risk of 4.4×10^{-5} for all commodities with sugarcane being the largest single contributor to total atrazine risk (Ref. 37). Excluding sugarcane, the total atrazine carcinogenic risk is estimated to be 2.2×10^{-5}. Other major risk contributors are milk, sweet corn, corn (other), red meat and eggs. The dietary cancer risk estimates for atrazine are provided in Table 1:

TABLE 1.—DIETARY CANCER RISK ESTIMATES FOR ATRAZINE

(FT = field trial data (parent, or parent + chloro). R = radiolabel data (total triazine ring)).

Commodity	Type Data Used	Anticipated Residue (ppm)	Percent Crop Treated	Exposure (mg/kg/day)	Upper Bound Cancer Risk Estimates
Corn, sweet	R	0.10	60	1.4×10^{-5}	3.1×10^{-6}
Corn, other	R	0.10	70	2.4×10^{-5}	5.3×10^{-6}
Eggs	R	0.01 (eggs, yolks) 0.009 (whites)	-	5.8×10^{-6}	1.3×10^{-6}
Guava	FT	0.01	10	-[1]	0
Macadamia nuts	FT	0.10	70	3.0×10^{-9}	6.6×10^{-10}
Milk	R	0.004	-	4.2×10^{-5}	9.2×10^{-6}
Millet	FT	0.68	1	-[1]	0
Pineapple	FT	0.03	20	4.0×10^{-7}	9.0×10^{-8}

TABLE 1.—DIETARY CANCER RISK ESTIMATES FOR ATRAZINE—Continued

(FT = field trial data (parent, or parent + chloro). R = radiolabel data (total triazine ring)).

Commodity	Type Data Used	Anticipated Residue (ppm)	Percent Crop Treated	Exposure (mg/kg/day)	Upper Bound Cancer Risk Estimates
Poultry meat	R	0.0006 (meat, fat) 0.002 (liver)	-	3.1×10^{-7}	6.8×10^{-8}
Redmeat	R	0.004 - 0.02[2]	-	9.3×10^{-6}	2.1×10^{-6}
Sorghum	R	0.13	70	2.2×10^{-6}	4.8×10^{-7}
Sugarcane	FT	0.16	80	1.0×10^{-4}	2.2×10^{-5}
Wheat	FT	0.02	1	2.8×10^{-7}	6.2×10^{-8}
Total					4.4×10^{-5}
Total (excluding sugarcane)					2.2×10^{-5}

[1] Exposure values for these commodities are extremely low.
[2] Range of values were used for meat, liver and kidney.

2. *Simazine cancer risk estimates.* Dietary cancer risk estimates for simazine are based on translated atrazine data for corn and animal commodities. The total estimated dietary risk from all commodities is 1.4×10^{-5} (from all registered commodities, the risk is 1.1×10^{-5}) (Ref. 38). (Note that estimates are based on half the limit of detection for most commodities.) The risk from simazine use on oranges is a major contributor to total risk, as is the risk from apples. Corn contributes only a small percent of the total simazine risk because of the low percent crop treated. The dietary cancer risk estimates for simazine are provided in Table 2:

TABLE 2.—DIETARY CANCER RISK ESTIMATES FOR SIMAZINE

(FT = field trial data (parent, or parent + chloro). R = radiolabel data (total triazine ring)).

Commodity	Type Data Used	Anticipated Residue (ppm)	Percent Crop Treated	Exposure (mg/kg/day)	Upper Bound Cancer Risk Estimates
Almonds	FT	0.10	45	1.3×10^{-7}	1.6×10^{-8}
Apples	FT	0.05	40	1.6×10^{-5}	1.9×10^{-6}
Avocados	FT	0.05	30	1.9×10^{-7}	2.3×10^{-8}
Bananas/Plantains	FT	0.02	10	4.7×10^{-7}	5.6×10^{-8}
Blueberries	FT	0.05	100	4.5×10^{-7}	5.4×10^{-8}
Caneberries	FT	0.05	100	7.2×10^{-7}	8.6×10^{-8}
Cherries	FT	0.10	45	1.7×10^{-6}	2.0×10^{-7}
Corn,sweet	R	0.10	5	1.2×10^{-6}	1.4×10^{-7}
Corn,other	R	0.10	2	6.8×10^{-7}	8.2×10^{-8}
Cranberries	FT	0.05	100	1.7×10^{-6}	2.0×10^{-7}
Currants	FT	0.05	100	2.7×10^{-8}	3.2×10^{-9}
Eggs	R	0.0003	-	1.8×10^{-7}	2.2×10^{-8}
Filberts	FT	0.10	100	4.0×10^{-8}	4.8×10^{-9}
Grapefruit	FT	0.05	45	5.2×10^{-6}	6.2×10^{-7}
Grapes	FT	0.05	35	3.9×10^{-6}	4.7×10^{-7}
Lemons	FT	0.05	50	1.0×10^{-6}	1.2×10^{-7}
Macadamia nuts	FT	0.10	100	5.0×10^{-9}	6.0×10^{-10}
Milk	R	0.00007	-	7.4×10^{-7}	8.9×10^{-8}
Olives	FT	0.05	18	1.0×10^{-7}	1.2×10^{-8}
Oranges	FT	0.05	45	4.8×10^{-5}	5.8×10^{-6}
Peaches	FT	0.05	35	3.8×10^{-6}	4.6×10^{-7}
Pears	FT	0.05	50	3.1×10^{-6}	3.7×10^{-7}
Pecans	FT	0.10	10	4.8×10^{-8}	5.8×10^{-9}
Plums	FT	0.10	12	7.4×10^{-7}	8.9×10^{-8}
Poultrymeat	R	0.0003	-	1.5×10^{-7}	1.8×10^{-8}
Redmeat	R	0.0001	-	2.3×10^{-7}	2.8×10^{-8}
Strawberries	FT	0.05	100	1.8×10^{-6}	2.2×10^{-7}
Walnuts	FT	0.10	50	2.4×10^{-7}	2.9×10^{-8}
Total (excluding cancelled uses)[1].					1.1×10^{-5}

TABLE 2.—DIETARY CANCER RISK ESTIMATES FOR SIMAZINE—Continued

(FT = field trial data (parent, or parent + chloro). R = radiolabel data (total triazine ring)).

Commodity	Type Data Used	Anticipated Residue (ppm)	Percent Crop Treated	Exposure (mg/kg/day)	Upper Bound Cancer Risk Estimates
Total (including cancelled uses)					1.4×10^{-5}

[1] Voluntarily cancelled uses include sugarcane, artichokes, asparagus and fish.

3. *Cyanazine cancer risk estimates.* The total estimated cyanazine dietary risk from all commodities is 2.9×10^{-5}. (Ref. 39). The largest contributor of risk is corn, both through the raw agricultural commodity itself and through secondary residues in meat, milk, poultry and eggs resulting from use of corn as a feed item. DuPont has requested voluntary cancellation for cyanazine use on sorghum, wheat and fallow cropland (Ref. 40). If cancellation of these uses becomes final, the total dietary risk will be 2.7×10^{-5}. Unlike atrazine and simazine, for which new residue data may refine dietary risks, no new residue data are necessary to refine the exposure estimates. The dietary cancer risk estimates for cyanazine are shown in Table 3:

TABLE 3.— DIETARY CANCER RISK ESTIMATES FOR CYANAZINE

Commodity	Anticipated Residue (ppm)	Percent Crop Treated	Exposure (mg/kg/day)	Upper Bound Cancer Risk Estimates
Corn	0.12	20	1.2×10^{-5}	1.2×10^{-5}
Cottonseed	0.09	5	9.3×10^{-8}	9.3×10^{-8}
Milk	0.00028 (milk) 0.000034 (non-fat solids)	-	1.2×10^{-6}	1.2×10^{-6}
Poultry and eggs	0.00232 - 0.00432[2]	-	3.1×10^{-6}	3.1×10^{-6}
Red meat	0.00345 - 0.0103[1]	-	1.0×10^{-5}	1.0×10^{-5}
Sorghum	0.10	5	1.2×10^{-7}	1.2×10^{-7}
Wheat	0.16	1	2.3×10^{-6}	2.3×10^{-6}
Total				2.9×10^{-5}

[1] Range of values were used for meat, meat byproducts, fat, liver and kidney.
[2] Range of values were used for meat, meat byproducts, fat, liver, kidney and eggs.

VI. Triazines Exposure in Drinking Water

A. Safe Drinking Water Standards—Health Advisory Levels and Maximum Contaminant Levels

To ensure public health and safety, EPA is responsible for establishing protective standards that limit the amount of pesticide contamination in drinking water. Maximum Contaminant Levels (MCL) are legally enforceable standards that represent the maximum permissible level of a contaminant in water delivered to any user of a public water system. Prior to establishing an MCL, the Safe Drinking Water Act (SDWA) requires that EPA establish a Maximum Contaminant Level Goal (MCLG) at the level at which no known or anticipated adverse effects on the health of persons occur over a lifetime of exposure and which allow an adequate margin of safety. Health Advisory Levels (HA) are non-enforceable guidelines that estimate the maximum amount of a contaminant that can be consumed without causing adverse effects over a specific period of time. Both the MCLG and the HA, while non-enforceable, are established as health-based reference points to provide guidance to ensure the safety of drinking water when an enforceable standard (MCL) is not available. The National Primary Drinking Water Regulations Phase II Rule requires water monitoring of all (60,000) community water systems and all (25,000) nontransient, noncommunity water systems. Quarterly samples must be taken consecutively each year. A water supply system is in violation if the running annual average at any sampling point exceeds the MCL. If the MCL is exceeded, water systems are required to notify the general public within 14 days and consumers directly within 45 days.

The MCL for a Group C carcinogen is generally based on the Reference Dose (RfD) for non-carcinogenic toxic effects. An additional onefold to tenfold factor is applied to the RfD to account for possible human carcinogenic effects. The MCL is based on a cancer risk range of 10^{-5} to 10^{-6} when non-cancer data are inadequate for deriving an RfD. EPA has established an MCL for atrazine at 3 µg/L (or 3 ppb) and for simazine at 4 µg/L (or 4 ppb). EPA expects to establish an MCL for cyanazine and is also considering the possibility of setting MCLs for triazine degradates as well as a combination of triazines.

When monitoring concentrations of contaminants in water supplies, the contaminant level or the annual average contaminant level is compared to the MCL established for that contaminant. If any single maximum contaminant concentration is greater than four times the MCL, it will automatically make the annual average of four quarterly samples greater than the MCL. Any water supply system reporting an average of any four successive quarterly samples greater than the MCL is considered to be out of compliance with the SDWA. The requirements of the SDWA do not govern decisions regarding the registrability of pesticides under FIFRA. However, standards such as MCLs, MCLGs, and HAs provide useful guidance to the Agency in identifying potential instances of unreasonable risks. Thus, if a pesticide is found at levels which exceed one of these levels, it is likely that use of that pesticide may exceed a Special Review trigger under the FIFRA regulations. Accordingly, detection of triazine residues in water at or above these levels is very pertinent to this Special Review.

1. *Atrazine Maximum Contaminant Level.* The MCL for atrazine of 3 µg/L (3 ppb) was established in 1991 (Ref. 41). Based on a Q_1^* of 2.2×10^{-1} (mg/kg/day)$^{-1}$, this MCL is associated with an estimated cancer risk level within the 10^{-5} range for drinking water (assuming a person consumes 2 liters of water per day containing atrazine at 3 µg/L over a 70–year lifetime) The MCL was calculated using the RfD of 0.005 mg/kg/day based on a NOEL of 0.5 mg/kg/day for decreased body weight in pups in a multi-generation reproduction study and an additional uncertainty factor of 10 to account for possible human carcinogenic effects. (The RfD was calculated using an uncertainty factor of 100: 10 for inter-species extrapolation and 10 for intra-species variability.) To account for other possible sources of exposure to atrazine, only 20 percent of the RfD was used to calculate the MCL.

In 1992, the EPA RfD Committee approved an increase in the atrazine RfD from 0.005 mg/kg/day to 0.035 mg/kg/day, based on evidence of decreased body weight in a chronic rat study with a NOEL of 3.5 mg/kg/day (Ref. 42). Based on the increase in the atrazine RfD, the registrant, Ciba, submitted a petition to the Administrator requesting a re-evaluation of the MCL and a stay on mandatory requirements including water monitoring (Ref. 43). The Agency considered, but has denied Ciba's petition to increase the MCL for atrazine. This denial takes into account a number of issues concerning the protection of public health, particularly possible cancer risks from total exposure to all triazines and their degradates (Ref. 44). The Agency is also reviewing its carcinogenicity guidelines and the Office of Water is revising its policy for regulating Category II chemicals which includes the Group C carcinogens.

2. *Simazine Maximum Contaminant Level.* In July 1990, an MCL Goal (MCLG) of 1 µg/L (1 ppb) was proposed for simazine based on a NOEL of 0.5 mg/kg/day for non-carcinogenic toxic effects in a 2–year rat study. Uncertainty factors applied included a threefold factor to account for a data gap with respect to the absence of adequate information to evaluate reproductive effects. This data gap for simazine was subsequently filled and since no effects were noted at the dose level (0.5 mg/kg/day) used to calculate the MCLG, the threefold safety factor was no longer required. Thus, the RfD has been increased from 0.002 mg/kg/day to 0.005 mg/kg/day. To account for other possible sources of exposure to simazine, only 20 percent of the RfD was used to calculate the MCL. An MCL of 4 µg/L was established for simazine (Ref. 45). Based on a Q_1^* of 1.2×10^{-1} (mg/kg/day)$^{-1}$, this value is associated with an estimated cancer risk level within the range of 10^{-5} for drinking water (assuming a person consumes 2 liters of water per day containing simazine at 4 µg/L over a 70 year period).

3. *Cyanazine Health Advisory.* EPA has not yet established an MCL for cyanazine. In 1988, the Agency established a lifetime Health Advisory (HA) for cyanazine at 10 µg/L (or 10 ppb). Based on a rat chronic toxicity study submitted to the Agency in 1991 that indicated cyanazine may cause mammary tumors in female Sprague-Dawley rats, an additional uncertainty factor of 10 was added to the reference dose calculations and the HA was changed from 10 µg/L to 1 µg/L, using an RfD of 0.002 mg/kg/day (decreased body weight gain and hyperactivity in rats). Based on a Q_1^* of 1×10^0 (mg/kg/day)$^{-1}$, this HA is associated with an estimated cancer risk level from drinking water in the 10^{-5} range (assuming a person consumes 2 liters of water per day containing cyanazine at 1 µg/L over a 70–year period). To account for other possible sources of exposure to cyanazine, only 20 percent of the RfD was used to calculate the HA. The registrant, DuPont, requested that EPA reconsider the change in the cyanazine HA before establishing an MCL. DuPont believes that the HA should be based on an 80 percent Relative Source Contribution rather than 20 percent as used by the Agency. (Ref. 46).

B. Environmental Fate, Chemistry, and Transport of the Triazine Herbicides

Of the three triazine herbicides, more environmental fate data are available for atrazine than for cyanazine or simazine simply because of the high level of atrazine use and the widespread research that has been conducted with atrazine. The parent triazine compounds as well as their degradates are expected to leach to ground water and to be transported to surface waters during runoff events that often occur after heavy rainfalls. Once the compounds leach into the subsoil and ground water, metabolism of the triazines slows considerably, because microbial populations are low and anaerobic conditions are not uncommon. Therefore, there is a potential for residues to accumulate in subsoils and ground water after many years of use and pose risks to humans consuming drinking water from contaminated ground water sources. When degradate residues are combined with parent residues, estimates of hazard to humans drinking contaminated drinking water and to aquatic organisms may be substantially increased.

Atrazine, simazine and cyanazine contain a symmetrical triazine ring and a chloro group attached to one of the carbons in the ring. The other two carbons carry substituted amino groups. All three triazines have an ethyl group on one of the amino groups, but the substituents on the other amino group differ for each triazine. For atrazine the substituent contains an isopropyl group and for simazine it is an ethyl group. For cyanazine, the substituent is a nitrile group that is very reactive and leads to the formation of degradates containing an amide and/or a carboxylic acid group. The reactivity of the nitrile group is reflected in the faster degradation and nature of degradates of cyanazine when compared to atrazine and simazine.

Based on the Agency's environmental fate data, atrazine and simazine are likely to be more persistent in water and in soils than cyanazine; however, all three triazines are mobile in a variety of soils. The three parent triazines persist in buffered aqueous media (pH 5, 7, and 9) for at least 30 days indicating that abiotic hydrolysis is not a rapid degradation process for these chemicals. Atrazine and simazine are resistant to direct photolysis, but photolysis does contribute to the degradation of cyanazine. In soils incubated under aerobic conditions, atrazine and simazine have half-lives of 150 and 110 days, respectively, whereas the half-life for cyanazine is 17 to 25 days. Under anaerobic conditions, the half-lives are even longer (about 2 years for atrazine and simazine and 108 days for cyanazine). The longer half-lives under anaerobic conditions imply that these herbicides may persist for an extended period of time in ground water and in oxygen-poor surface waters.

Atrazine and simazine follow similar degradation pathways with both parent compounds forming hydroxy analogues and des-alkylated chloro degradates which may persist in soil and water for many months. The hydroxy degradates tend to be less mobile than parent or des-alkylated degradates. Unlike atrazine and simazine, cyanazine does not degrade to a hydroxy analogue, but instead produces degradates containing an amide and/or a carboxylic acid group formed from the nitrile group. Hydroxy analogues of these degradates are also formed, but to a lesser extent. Although cyanazine can produce chloro degradates that are common to atrazine and simazine, they have been shown to be only very minor degradation products, at least in laboratory studies.

The parent triazine compounds as well as their degradates (particularly the chloro degradates) are expected to leach to ground water and to be transported to surface waters especially during runoff events that often occur after heavy rainfalls. Because metabolic processes tend to decrease with increasing anaerobic conditions, residues of parent compounds and degradates will not break down as rapidly and will accumulate as the compounds are transported into deeper soil profiles and ground water or in lakes and reservoirs.

C. Drinking Water Exposure

Drinking water for human consumption may be obtained from both surface water and ground water sources. Because surface and ground water sources often are interconnected, contamination of one source may result in contamination of the other. Data which demonstrate the presence of the triazines in ground and surface water as well as in precipitation are discussed in the following sections. In general, the studies used in the Agency's evaluations were designed to monitor for specific chemicals and not to estimate populations exposed to them.

It should be noted that EPA is also concerned about potential human exposure to triazine degradates resulting from consumption of drinking water. Although limited information is available about their occurrence in ground and surface water and no MCLs or HAs have been established, monitoring studies increasingly indicate the presence of triazine degradates in ground and surface waters in measurable quantities in many locations.

1. *Surface water*—a. *Surface water monitoring.* The Agency has considered over 15 sets of data on the concentrations of triazine pesticides in raw and finished surface waters, most of which were obtained from the 12-state midwestern corn belt where the majority of the annual triazine use occurs. These data include field monitoring studies, literature reviews and data submitted under section 6(a)(2), the provision of FIFRA which requires registrants to inform the Agency of potentially adverse effects resulting from a pesticide. Information from 10 monitoring studies and 2 additional submissions of section 6(a)(2) data have been the primary data used in this analysis; the study-specific sampling characteristics and results of these reports are summarized in Table 4 (Refs. 47, 48, 49, 50, and 51):

TABLE 4.—SUMMARY OF SURFACE WATER MONITORING STUDIES

Study	Sampling locations	Sampling frequency	Chemical	Percentage of samples with detections	Two highest among maximum concentrations from each location (µg/L)	90th percentile concentration of all maximum detections[1] (µg/L)	Median concentration of all maximum detections[2] (µg/L)	Percentage of sites with maximum concentrations equal to or greater than 4 times MCL
Smith et al (Monsanto, 1987).	30 water supplies in midwestern corn belt (finished water)	Weekly April thru Aug./Sept. (1986)	Atrazine	80.3	22.5, 16.3	13	3.57	16.7%
			Cyanazine	80.3	6.14, 5.61	4.95	0.59	13.3%
			Simazine	80.3%	2.54, 2.23	1.58	0.32	
Baker (1988)	8 Ohio tributaries of Lake Erie	Almost daily April thru Aug. (1982-1985)	Atrazine	Not provided for this study	245, 226	48.4	13.6	50.0%
			Cyanazine	Not provided for this study	86.1, 23.1	14.9	3.4	40.0%
			Simazine	Not provided for this study	10.8, 6.93	4.95	0.78	
Squillace and Engberg (USGS, 1988).	6 locations in Cedar River Basin	Approx. monthly in May 1985 thru Nov. 1985	Atrazine	91.0%	16, 16	16	7.3	25.0%
			Cyanazine	35.0%	8.7, 8.1	8.6	1.8%	41.7%
Roux (Ciba Geigy, 1988).	14 locations in midwestern corn belt (rivers/streams)	Bimonthly in late spring and early summer; monthly at all other times(1986-1987)	Atrazine	90.0%	30.5, 30.5	30.1	2.7	17.9%
Moyer and Cross (1988).	30 locations in Illinois (rivers/streams)	4-7 samples per location per year (1986-1988)	Atrazine:	75.1%				
			1986		16, 13	11	3.3	6.67%
			1987		24, 18	13	2.3	13.3%
			1988		39, 19	3.8	1.0	6.67%
			Cyanazine:	75.1%				
			1986		9, 6.2	5.7	0.66	20.0%
			1987		28, 17	11	1.5	13.3%
			1988		38, 31	5	0.45	10.0%

TABLE 4.—SUMMARY OF SURFACE WATER MONITORING STUDIES—Continued

Study	Sampling locations	Sampling frequency	Chemical	Percentage of samples with detections	Two highest among maximum concentrations from each location (µg/L)	90th percentile concentration of all maximum detections[1] (µg/L)	Median concentration of all maximum detections[2] (µg/L)	Percentage of sites with maximum concentrations equal to or greater than 4 times MCL
Keck (1991)	7 locations in the Missouri River Basin	Daily May thru July (1991)	Atrazine	Not provided for this study	11.1, 10.7	NA	8.28	0.0%
			Simazine	Not provided for this study	0.48, < Detection Limit (DL)	NA	< DL	
Goolsby and Thurman (1991).	142 locations across 10 midwestern states (rivers/streams)	1-3 samples per year (1989)	Atrazine	98.4%	108, 71.6	27.2	3.8	26.4%
			Cyanazine	63.6%	61.2, 45.2	10.9	0.99	27.1
			Simazine	46.5% (Post-appl.)	6.99, 4.88	0.95	0.07	
Goolsby et. al. (1991).	8 locations in Mississippi River Basin	Biweekly May thru Aug.; Weekly Apr. and Sept.thru Dec. (1989)	Atrazine	98.0%	10, 9.2	NA	5.7	0.0%
			Cyanazine	42.8%	7.3, 6.6	NA	4.4	50.0%
			Simazine	25.6%	0.72, 0.48	NA	0.12	
Dupont 6(a)(2) (1991).	1 location in West Lake, Iowa	Weekly May thru Nov. 1991	Atrazine	100%				
			Raw		7.9, 7.3	7.18	6.2	NA
			Finished		8, 7.9	7.78	6	NA
			Cyanazine	100%				
			Raw		15.1, 14	13.9	11.7	NA
			Finished		15.3, 14.5	14.3	11.1	NA
Ciba-Geigy 6(a)2 (1994).	7 Illinois water supplies (finished water)	Bimonthly June 1993 thru May 1994	Atrazine	94.4%	68, 33	NA	22	100%
Blasland and Bouck (1991).	Summary of Hoover Reservoir Ohio data	Monthly 1985-1991	Atrazine	Not provided for this study	11.9, 10.3	7.22	0.83	0.0%
Kloibel (1993) ..	17 locations at Rathbun Reservoir	Five times April thru Dec. 1990	Atrazine	Not provided for this study	4.94, 4.31	NA	4.27	NA
Concentration Ranges (µg/L).			Atrazine		4.3 - 245		0.83 - 22	
			Cyanazine		5.6 - 86.1		0.45 - 4.4	
			Simazine		0.48 - 7		0.07 - 0.78	

[1] Reflects the concentration at which 10 percent of the maximum detections at each sampling location are above and 90 percent are below.
[2] Reflects the concentration at which 50 percent of the maximum detections at each sampling location are above and 50 percent are below.

The Agency's major findings related to surface water can be summarized as follows:

• Of the triazine herbicides, atrazine and cyanazine were detected most often in both untreated and treated surface water in the midwestern corn belt. Simazine was detected less often and at lower concentrations than atrazine and cyanazine in the same region. The frequency of detects is more likely related to the total amount of each triazine used rather than a difference in their chemical and physical properties. The Agency has not received or reviewed any data on the concentrations of simazine in surface waters which drain areas of heavy simazine use on orchards and nut trees.

• Atrazine, atrazine degradates, simazine, and cyanazine residues often occur in the same water samples at various levels depending on herbicide usage in that given watershed. The

cumulative effects of all of these triazine compounds on humans from drinking water or on aquatic and terrestrial ecosystems are assumed to be additive.

• Atrazine is detected in a high percentage of surface water samples collected from numerous locations within the corn belt even in early spring before application and in late fall and winter many months after application. Cyanazine, and to a lesser extent, simazine, are detected in a lower but still relatively high percentage of surface water samples collected during the first couple of months post-application. However, unlike atrazine, they are generally not detected in high percentages of samples collected in early spring (pre-application) or in fall or winter many months after application.

• After peaking one to several times from early May to early July, concentrations of atrazine and cyanazine in streams and rivers typically decline rapidly by late July to August to concentrations less than 1 µg/L and remain at those levels until the application and post-application periods of the following spring.

• While most of the available data are on streams and rivers, there are limited data on lakes and reservoirs. Atrazine, and to a lesser extent cyanazine, concentrations have been reported to remain elevated at several µg/L almost year round during some years in these bodies of water in the midwestern corn belt including Hoover Reservoir in Ohio, Rathbun Reservoir and West Lake in Iowa, Perry and Tuttle Creek Reservoirs in Kansas and Otter Lake in Illinois. This may be due at least in part to the resistance of atrazine and cyanazine to abiotic degradation coupled with low microbiological activities and long hydrological residence.

• Results of a number of studies of streams and rivers of the corn belt indicate that atrazine and cyanazine concentrations typicallyincrease rapidly from pre-application concentrations of less than 1 µg/L to post-application peak concentrations of at least several µg/L. Peak concentrations frequently exceed 10 µg/L and sometimes exceed 20 µg/L. Peak concentrations exceeding 50 µg/L appear to be rare, but peak concentrations of atrazine exceeding 100 µg/L (up to 245 µg/L) and of cyanazine exceeding 50 µg/L (up to 86 µg/L) have been reported.

• Peak concentrations generally occur between early May and early July often in conjunction with or shortly after the first few post-application runoff events. In areas where tile drainage and/or groundwater inflow contribute substantially to the loading of atrazine and cyanazine to surface waters, secondary peaks may occur substantially after a major runoff event.

• Peak concentrations of triazines are generally greater in surface waters draining small watersheds than in those draining large watersheds, but triazine concentrations tend to remain elevated longer in surface waters draining large watersheds.

• Maximum and seasonal-annual time weighted mean concentrations of atrazine and cyanazine in surface water at the same sampling location often vary substantially (sometimes > 10X) from year to year depending in part upon the intensity, duration, and timing of post-application runoff events.

• Maximum observed concentrations of simazine in the midwestern corn belt are less than 4 times its MCL.

• For atrazine and cyanazine, many of the studies reviewed by the Agency have significant percentages of sampled locations with several month to annual means exceeding the atrazine MCL and the cyanazine HA. However, in many cases where a spring-summer atrazine or cyanazine mean exceeds the atrazine MCL or cyanazine HA, the annual mean would likely not exceed the health standard.

• Contamination of estuarine and marine waters by triazines have also been reported. Data show that for the period April 1, 1991, to March 31, 1992, approximately 1.6 percent of the atrazine, 1.6 percent of the cyanazine, and 2.7 percent of the simazine applied to the Mississippi River Basin in 1991 were transported to the Gulf of Mexico (Ref. 52). In a literature review of atrazine in the Chesapeake Bay and major rivers draining into it, a high percentage of detects (72 percent) were reported in over 600 samples collected from 1976 to 1991, but only 3 concentrations were greater than 3 µg/L (up to 5.9 µg/L) (Ref. 53).

b. *Triazine degradates in surface water.* Atrazine chloro degradates (desethyl atrazine and deisopropyl atrazine) have been detected in midwestern stream and river sites at concentrations of an order or more magnitude less than that of the parent atrazine (Ref. 54). This study suggests that the concentration of atrazine degradates is generally less than 10 percent of the parent atrazine concentration in flowing surface water, but may be higher in lakes and reservoirs. Because they are not typically monitored for, the Agency has no data on the concentration of the degradates of either cyanazine or simazine in surface water. It should be noted that atrazine and simazine can generate two chloro degradates in common. The United States Geological Survey (USGS) has recently focused on detections of cyanazine in surface water, but the final report is not yet available.

c. *Surface water exposure.* The available data suggest that a number of surface source drinking water supply systems within the corn belt will have annual average atrazine concentrations exceeding the atrazine MCL of 3 µg/L and/or annual average concentrations of cyanazine exceeding the cyanazine HA of 1 µg/L. Current estimates may underestimate exposure because they do not include triazine degradates which could increase exposure levels by 10 percent; they may overestimate exposure in that they are annual average concentrations rather than annual time-weighted means. The Agency will be able to refine estimates of drinking water contamination with triazines with additional information that will be obtained from monitoring required by the SDWA. Similarly, the Agency will soon have access to data on simazine concentrations from recently-begun surface water monitoring in Florida and California, areas of high simazine use on fruits and nuts. The SWDA does not currently require water systems to sample and analyze for cyanazine.

2. *Ground water*— a. *Ground water monitoring.* To evaluate potential triazine exposure through contaminated ground water, EPA has reviewed monitoring data that include information submitted to the Agency by pesticide registrants, States, the USGS as well as information compiled in the EPA National Pesticide Survey of Drinking Water Wells (NPS) and studies summarized in OPP's, Pesticides in Ground Water Database (PGWDB). The Agency's report, Water Resources Impact Analysis for the Triazine Herbicides, tentatively scheduled for release late in 1994, describes the studies and summarizes the findings (Ref. 47). A brief description is provided of the major sources of data that the EPA has used to evaluate exposure to triazine herbicides through ground water contamination.

The EPA PGWDB (1992) contains data from 153 separate studies with about 96 percent of the data from wells that serve as sources of drinking water. The NPS was a statistically designed one-time sampling of both larger community wells and smaller rural domestic wells nationwide that are currently used as sources of drinking water. It was designed to estimate the proportion of wells nationally that contain pesticides or degradates. The National Alachlor Well Water Survey (NAWWS) was conducted by the registrant of alachlor,

Monsanto, and contains data from a one-time sampling of private rural wells limited to alachlor use areas. Estimates of atrazine residues in ground water can be obtained from the results of this study because alachlor and atrazine use areas coincide fairly closely; however, this is not the case with simazine and cyanazine.

A number of States have also initiated ground water monitoring programs designed to evaluate the impact of pesticides and their degradates on ground water quality. Among these studies are Iowa's State-Wide Rural Well Water Survey (SWRL) and Wisconsin's Rural Well Survey. The Iowa study includes data on atrazine, two chloro degradates (desethyl atrazine and desisopropyl atrazine) and cyanazine; the Wisconsin study includes data on atrazine and three chloro degradates (desethyl atrazine, desisopropyl atrazine, and diamino chlorotriazine). California's Well Inventory Database is a compilation of reports of any pesticide testing done on well water in the state. Recently, additional ground water monitoring has been initiated by Ciba in 22 states. Preliminary reports indicate that triazine residues have been found in many drinking water wells nationwide (Ref. 55).

i. *Atrazine detections.* In OPP's PGWDB, atrazine is the fifth most often detected pesticide (following aldicarb and its metabolites, carbofuran, ethylene dibromide and DBCP) with detections in 32 out of 40 states in which samples were collected. Of 1,512 wells that contained residues of atrazine at the time this data were compiled (1992), 172 wells (11 percent) were found to have concentrations that exceed the MCL of 3 µg/L. Concentrations ranged from trace levels to 1,500 µg/L.

In the NPS, atrazine was the second most frequently found pesticide. Based on the data obtained in the NPS, EPA estimated that atrazine occurred in 70,800 (0.7 percent) rural domestic wells nationwide and in 1,570 (1.7 percent) community supply wells nationwide.

Monsanto's NAWWS study was conducted to estimate the proportion of private, rural domestic wells in the alachlor use area that contain detectable concentrations of alachlor. Monsanto added four other herbicides as analytes including atrazine, simazine and cyanazine. Atrazine was the most frequently found pesticide and was estimated to be present in 12 percent of wells in the alachlor use area. Monsanto estimated that concentrations exceeded the MCL in 0.1 percent of the wells in the alachlor use area. According to NAWWS data, approximately 12 percent of the population in the alachlor use area (2.4 million people) is exposed to parent atrazine residues less than 0.2 µg/L (0.2 µg/L was the limit of detection for atrazine the study). Approximately 184,000 people in this area are exposed to residues greater than or equal to 0.2 µg/L.

In the state studies reviewed for this Position Document, atrazine is one of the most frequently detected pesticides. In the Iowa SWRL, it was the most frequently detected pesticide (4.4 percent of rural private drinking water wells) and of all pesticides found, atrazine most often exceeded the MCL. It was estimated that atrazine (parent only) would be detected in 0.6 percent of wells statewide at concentrations that exceed the MCL. Additional detections of chloro triazine degradate increases the total number of wells with detections and would likely increase the exposure estimates.

In Phase 1 of Wisconsin's ground water study, 218 wells in 45 counties (almost 28 percent) were found to contain detectable (0.1 µg/L or greater) triazine residues, predominantly atrazine parent. Resampling of these well sites for Phase 2 indicated that 49.1 percent of the 236 wells sampled contained atrazine parent at a level that exceeded the state's Preventive Action Limit of 0.35 µg/L. The State Enforcement Standard of 3.5 µg/L was exceeded in 6.4 percent of the wells on the basis of the parent atrazine concentration alone.

Atrazine is the third most frequently detected pesticide in California's Well Inventory Database. Confirmed detections resulting from routine agricultural use have reportedly been found in 119 wells. Residues of parent atrazine have been reported in 21 counties at concentrations ranging from 0.02 to 8.5 µg/L.

ii. *Simazine detections.* In OPP's PGWDB, simazine was the eighth most often detected pesticide with detections reported in 19 out of 30 states in which samples were collected. Of the 486 wells that contained residues, a total of 36 (7 percent) had concentrations that exceeded the MCL of 4 µg/L. Concentrations ranged up to 67 µg/L.

Simazine was also one of the most commonly found pesticides in the NPS. Based on these data, simazine is estimated to occur in 25,000 (0.2 percent) rural domestic wells and 1,080 (1.1 percent) community supply wells. The lower percentage of wells with simazine detections compared to those with atrazine detections is probably due to lower simazine use in surveyed areas since the two chemicals have a similar potential to reach ground water.

Monsanto's NAWWS data on simazine estimates that approximately 400,000 people are exposed to at least 0.03 µg/L of this herbicide in ground water, but none at levels above the MCL of 4 µg/L. No simazine degradation products were analyzed. Monsanto states that this may not be a good estimate of simazine occurrence because the use areas of simazine and alachlor do not closely coincide.

Simazine was the most frequently detected pesticide in California's Well Inventory Database. Confirmed detections resulting from routine agricultural use have reportedly been found in 296 wells. Residues of simazine parent only have been reported in 20 counties at concentrations ranging from 0.02 to 49.2 µg/L. Simazine was not an analyte in the Iowa State-Wide Rural Well Water Survey or the Wisconsin Rural Well Survey.

iii. *Cyanazine detections.* Fewer monitoring data exist for cyanazine in ground water than for atrazine and simazine. In OPP's PGWDB, cyanazine was the fifteenth most often detected pesticide with detections in 15 out of 27 states in which samples were collected. Of 155 wells that contain residues, a total of 22 (14 percent) reported cyanazine concentrations that exceed the HA of 1 µg/L. Concentrations range from trace levels to 29 µg/L.

In Iowa's State-Wide Rural Well Water Survey, cyanazine was the fifth most frequently detected pesticide out of 27 analytes. Approximately 1.2 percent of rural private drinking water wells in Iowa were estimated to be contaminated with cyanazine parent. The maximum concentration detected was 0.84 µg/L.

NAWWS estimates that detectable levels of cyanazine are expected to occur in 0.3 percent of rural domestic wells in counties where alachlor is used. As in the case of simazine, these estimates may not be accurate because the use areas of cyanazine and alachlor do not closely coincide. However, using this information, OPP estimates that about 60,000 people are exposed to at least 0.1 µg/L of cyanazine in ground water.

No detections of cyanazine were reported in the NPS; however, the minimum detection limit in that study was high (2.4 µg/L) when compared to the HA of 1 µg/L. Cyanazine was not an analyte in the Wisconsin study. No confirmed detections of cyanazine are reported in the California database.

iv. *Triazine degradates in ground water.* Only limited information is

available on the occurrence or level of triazine degradates in ground water. Data on cyanazine degradates, in particular, are rarely sought. The most significant information on degradation products comes from the Iowa and Wisconsin state surveys, and from a ground water reconnaissance study conducted by the USGS. In contrast with the levels of degradates found in rivers and streams (up to 10 percent of the level of the parent), levels of the degradates in ground water can be much more significant; total triazine concentrations in ground water can double or triple, when chloro degradates and parent are both considered.

In the Iowa State-Wide Rural Well Water Survey, two of the three major chloro degradates of atrazine, desethyl and desisopropyl, were both detected at approximately the same rate (3.5 percent and 3.4 percent, respectively) as atrazine parent (4.4 percent). Degradates were commonly detected in combination with atrazine, but over half of the metabolite detections occurred when atrazine parent was not present. Because of the incidence of detections of triazine degradates, the percentage of wells that were found to contain triazine residues approximately doubled from 4.4 percent (atrazine alone) to 8 percent (total triazine residues) when comparing parent only detects with parent plus degradate detects.

In the Wisconsin Rural Well Survey, degradates accounted for 67 percent of total triazine residues detected. Almost 92 percent of wells that were resampled in Phase 2 of the study contained a combination of parent and degradate residues. Two atrazine chloro degradates, desethyl atrazine and di-amino *s*-triazine, were found with approximately the same frequency as atrazine parent (83 to 88 percent) at concentrations of up to 8.8 and 9.9 µg/L, respectively. A third chloro degradate, desisopropyl atrazine, was detected less frequently (60.6 percent) and at lower concentrations (0.1 to 2.6 µg/L). As discussed previously, atrazine parent concentrations exceeded the Wisconsin enforcement standard in 6.4 percent of the wells, while combined concentrations of atrazine and chloro degradates exceeded the State Enforcement Standard (ES) in 29 percent of the wells resampled, or 3 percent more than the number of original wells exceeding the ES.

Preliminary results of a recent USGS study of herbicides and nitrates in near-surface aquifers in the midcontinental United States indicate that the degradate desethyl atrazine was the most frequently reported compound (18.1 percent of wells), followed by atrazine (17.4 percent) and desisopropyl atrazine (5.7 percent) (Ref. 56). Approximately 25 percent more wells contained total triazine residues than wells in which atrazine parent alone was found. No analyses were done for the third chloro degradate, diamino chlorotriazine. This study differs from the NPS and NAWWS studies in that it was not statistically designed, and it sampled ground water, not just ground water used as a source of drinking water.

b. *Ground water exposure.* The triazine chemicals have had a major impact on ground-water resources. In atrazine use areas, ground-water contamination is widespread at levels well below the Maximum Contaminant Level, but occurs at higher levels in localized areas. This contamination may persist for decades or longer in ground water. With currently available analytical methodology, atrazine is the most frequently detected pesticide in ground water in the midwestern United States, including Nebraska, Iowa, Illinois, Indiana, Minnesota, and Wisconsin. The Pesticides in Ground Water Database 1992 Report indicates that atrazine has been detected in 32 out of the 40 states that have reported monitoring data. EPA estimates that, based on results of the NPS and the NAWWS, between 2 million and 3 million people using ground water as their primary drinking water source are exposed to atrazine at average concentrations of at least 0.2 µg/L. *S*-triazine herbicides other than atrazine (simazine, cyanazine, and prometon) have had much less cumulative impact on ground-water quality than atrazine, probably because they are less intensively used. Another important factor leading to this conclusion is that they have not been as extensively studied. Recent information also indicates that at least three triazine metabolites can constitute a significant component of the total residues in ground water. The impact on ground water quality and human health from these metabolites is still unknown, but there is the potential that these compounds could contribute to the toxic effects on humans and the environment. In addition, since surface water and shallow ground water are often hydraulically connected, rivers contaminated with *s*-triazines can contaminate nearby wells; alternatively, contaminated ground water can supply water to rivers.

The USGS has recently focused on detections of cyanazine degradates in groundwater. However, a final report has not yet been published. According to the NAWWS data, approximately 12 percent of the population in the alachlor use area (2.4 million people) are exposed to atrazine residues of less than 0.2 µg/L. Approximately 184,000 people in this area are exposed to residues greater than or equal to 0.2 µg/L (limit of detection for the study). Monsanto's NAWWS data on simazine estimates approximately 400,000 people are exposed to at least 0.03 µg/L of this herbicide in ground water, but none at levels above the MCL of 4 µg/L. Using the NAWWS data on cyanazine, OPP estimates that about 60,000 people are exposed to at least 0.1 µg/L in ground water. As mentioned earlier, the exposure numbers for simazine and cyanazine may not be good estimates because the use areas of these chemicals do not closely coincide with those of alachlor.

D. Triazines in Precipitation

Triazines are also found in precipitation. These residues in rainfall are expected to be additive to the triazine residues already found in surface water. Therefore "triazine rainfall" reaching surface water may also increase the levels of contamination in drinking water. Triazine herbicides have been detected in precipitation samples in a study of 23 states in the upper midwest and northeast United States (Ref. 57). Atrazine was the most frequently detected herbicide, followed by alachlor, desethyl atrazine and metolachlor. Concentrations ranging from 1 to 3 µg/L of atrazine were measured in a few samples; however, most precipitation-weighted herbicide concentrations varied between 0.2 and 0.4 µg/L in May and June samples. Another study conducted in Isle Royale National Park, Michigan, showed that rainwater samples contained atrazine residues ranging from trace levels to 0.05 µg/L (Ref. 58). Atrazine residues ranging up to 1.5 µg/L were also detected in rainwater in the rural areas of Iowa with large variations in the pesticide content of precipitation between individual storms (Ref. 59).

VII. Risks from Exposure to Triazine-Contaminated Drinking Water

A. Risk Estimates at the Maximum Contaminant Level/Health Advisory

Triazines pose a potential drinking water risk to exposed human populations. Monitoring data indicate that there is extensive triazine contamination of ground water and surface water used for drinking purposes. The estimates of the levels of exposure would be expected to increase if complete monitoring data were available for the degradates. The extent of the human population exposed to

these contaminated drinking water sources (i.e. exposure greater than the MCL) is not certain. However, 29 million people use surface water for drinking water in 11 corn belt states with the remainder of the people using ground water for drinking purposes.

As stated previously, EPA has established MCLs for atrazine and simazine at 3 µg/L and 4 µg/L, respectively, and an HA for cyanazine at 1 µg/L. When establishing MCLs, the Agency assumes a Relative Source Contribution (RSC) of at least 20 percent in the drinking water and 80 percent from other sources. (The RSC refers to the percentage of the RfD allocated to a particular source, i.e. water contributes 20 percent of the total exposure). As yet, there are no MCLs established for triazine degradates and estimates of risk from consuming water contaminated by the triazine herbicides do not include the potential risks associated with exposure to their degradates. Estimating carcinogenic risk from drinking water assumes lifetime (70 years) consumption of 2 liters of water per day by a 70 kg human.

Based on the cancer potency (Q_1*) and exposure (i.e. 2 L/day) assumptions used to calculate carcinogenic risk, exposure to atrazine in drinking water at the MCL (3 µg/L) results in an upper bound excess carcinogenic risk of 1.9×10^{-5}. Exposure to simazine in drinking water at the MCL (4 µg/L) results in an upper bound excess carcinogenic risk of is 1×10^{-5}. Exposure to cyanazine in drinking water at the HA (1 µg/L) results in an upper bound excess carcinogenic risk of 2.5×10^{-5}.

B. Risk Estimates Based on Monitoring Data

Drinking water risks from ground or surface water sources are not typically included in EPA's estimates of dietary (food) risk due to lack of adequate monitoring data, fluctuations in exposure levels geographically, poor consumption information and other factors. Since there are surface and ground water monitoring data available for the triazines, these data have been used to develop more realistic estimates of triazine drinking water risks to exposed populations. However, data are not available to allow OPP to determine the number of people who actually consume surface water contaminated with the triazines.

1. *Surface water sources.* To estimate risks from surface water exposure, two monitoring studies were considered. The first study monitored for 15 pesticides, including atrazine and cyanazine, in surface water at 30 stations (flowing water) in Illinois (Ref. 60). Because the Illinois study did not sample for simazine, a second study that was conducted primarily to provide information on the occurrence of alachlor in drinking water, but also monitored atrazine, simazine and cyanazine, was used to determine the average time-weighted mean concentrations (TWMC)(averages over 30 supplies) for simazine. The average TWMCs are 0.84 µg/L for atrazine, 0.23 µg/L for simazine and 0.43 µg/L for cyanazine; the high end or 90th percentile TWMCs are 1.88 µg/L for atrazine, 0.31 µg/L for simazine and 1.66 µg/L for cyanazine. The Agency estimated exposure for mean tapwater intake and 90th percentile consumption using values of 22.6 and 39.8 g water/kg bwt/day, respectively. Consumption values were derived from USDA's 1977-78 Nationwide Food Consumption Survey (Ref. 61). The use of this water consumption value may underestimate risk because it does not include consumption of "commercial water" added during the manufacture and processing of products such as sodas and beer. The excess individual lifetime cancer risk estimates from both average and 90th percentile exposure to triazines in surface water are shown in Table 5 (Ref. 60):

TABLE 5.—EXCESS INDIVIDUAL LIFETIME CANCER RISK ESTIMATES FROM CONSUMPTION OF SURFACE WATER

	Mean Exposure	90th Percentile
Atrazine ..	4.2×10^{-6}	1.6×10^{-5}
Simazine .	6.2×10^{-7}	1.5×10^{-6}
Cyanazine	9.7×10^{-6}	6.6×10^{-5}

It is important to note that these cancer risk estimates for surface water are geographically restricted and do not apply to the entire U.S. population, but are representative values for individuals residing in the corn belt region. In other regions of the country where the triazines are not used, there will be no risk from drinking water, while in some areas (i.e., Florida and Central Valley of California) simazine concentrations are likely to be much higher than in the corn belt.

2. *Ground water sources.* To estimate risks from ground water exposure, detections from NAWWS monitoring data were used with the same drinking water intake assumptions discussed earlier for surface water. The NAWWS data provide the best estimates of exposure based on currently available ground water information.

Assuming Q_1*s of 2.2×10^{-1} (mg/kg/day)$^{-1}$ for atrazine; 1.2×10^{-1} (mg/kg/day)$^{-1}$ for simazine; and 1.0×10^{0} (mg/kg/day)$^{-1}$ for cyanazine, the upper bound excess individual lifetime cancer risk estimates for the triazines are provided in Table 6 (Ref. 62):

TABLE 6.—EXCESS INDIVIDUAL LIFETIME CANCER RISK ESTIMATES FROM CONSUMPTION OF GROUND WATER

	Mean Exposure	90th Percentile
Atrazine ..	9.9×10^{-7}	1.8×10^{-6}
Simazine .	8.1×10^{-8}	1.4×10^{-7}
Cyanazine	2.3×10^{-6}	4.0×10^{-6}

Because these estimates apply only to those individuals consuming triazine-containing drinking water from rural domestic wells in the alachlor use area, they may underestimate risk. In addition, because the NAWWS residue values used to estimate risk are lower bound estimates, cancer risks may be higher. Furthermore, it is important to note that the exposure estimates from the NAWWS data do not include triazine degradates; their inclusion could increase the exposure estimates, thereby increasing the risk.

C. Registrants' Responses to Preliminary Notification Concerning Drinking Water Risks and Agency Comments

Ciba and DuPont have responded to the Agency's preliminary notification of possible Special Review for drinking water risks associated with triazine contamination. The registrants' responses and the Agency's comments are detailed below.

In DuPont's response, it stated that a voluntary cyanazine exposure reduction program proposed in 1993 was developed in close cooperation with the Agency and that the program is aimed at reducing ground and surface water contamination with cyanazine from agricultural point and non-point sources. DuPont developed the risk reduction program to address Agency concerns regarding surface water detections in exceedance of the current cyanazine HA of 1 µg/L resulting from rainfall run-off events. DuPont contends that their program will significantly reduce runoff contamination of drinking water supplies. A report on the effectiveness of the risk reduction measures will be available to the Agency in the Fall of 1994.

The Agency believes that DuPont's 1993 proposal was a positive step towards reducing ground and surface water contamination, but clearly indicated when accepting the proposal

that these were considered to be only interim measures. The Agency has no information that shows that these risk reduction measures have reduced contamination to an acceptable level. During the Special Review, the Agency will evaluate the report that DuPont will submit and determine the effectiveness of these measures and whether or not additional measures will be necessary.

The Agency remains concerned about the occurrence of cyanazine at exceedances of its HA in ground water. Both ground water and surface water supplies serve as sources for drinking water and are often interconnected. Data from the Pesticides in Ground Water Data Base estimated that approximately 57 surface water systems exceeded the HA compared with about 360 ground water systems. Although some ground water systems may be influenced by surface water, and may show lower levels of cyanazine as a result of mitigation measures, the Agency is still concerned that most ground water systems would remain vulnerable to contamination from cyanazine leaching. Furthermore, the contribution of cyanazine degradates to the total triazine residue in both surface and groundwater is still unknown because no published data on cyanazine degradate monitoring are available at the present time. However, the Agency is aware of ongoing research by the USGS in this area and will evaluate all new information as it becomes available (Ref. 56).

DuPont also stated that it believed that the HA for cyanazine should be increased and has petitioned the Office of Water to reevaluate and raise the HA based upon an 80 percent Relative Source Contribution (RSC) from water.

In April 1994, the Agency denied DuPont's request to change the RSC used in deriving the cyanazine HA. The Agency believes that it is prudent to use a 20 percent RSC value rather than 80 percent for the following reasons: (1) the Agency RSC workgroup is still discussing multimedia exposure and the allocation of the RSC from drinking water, and (2) there are uncertainties associated with the contribution of total triazines and their degradates to the total exposure. (Ref. 63).

Ciba contends that, based on currently available health and safety data for atrazine and simazine, no significant health risks result from exposure to contaminated drinking water. Ciba also states that it has designed and implemented a 22-state ground water monitoring program to define the presence of atrazine, simazine and their chloro metabolites in water. Ciba believes that most water supply systems can comply with a MCL of 3 µg/L for atrazine but that some systems will be above the standard at some times during any given year, and in some cases, on an annual basis. Ciba petitioned the Agency to reevaluate the MCL for atrazine based on the revised RfD established for atrazine on October 1, 1993, citing the increase in the RfD as the basis. Ciba also claimed an inconsistency in the Agency's views regarding water systems exceeding the established MCL. Ciba recounted that during a meeting with the Office of Water, there was no urgency on behalf of the Agency to revise the MCL because water utilities nationally would not have a problem complying with the current standard. Ciba points out that, on the other hand, the Agency has issued the preliminary notification because of concern for compliance with the current standard. For simazine, Ciba believes the current monitoring data demonstrate that widespread contamination of drinking water does not exist and that results of the ongoing program will support this position.

The Agency has reviewed Ciba's position and has a number of comments. The positions of the Office of Water and the Office of Pesticide Programs are not inconsistent in that both are concerned about health risks from drinking water and both offices have chosen to take a position most protective of public health. As discussed previously, the Agency recently has denied Ciba's request to revise the MCL for atrazine. For both atrazine and simazine, the Agency is initiating this Special Review because of data that show levels of ground and surface water contamination which could result in unacceptable drinking water risks.

VIII. Triazine Non-dietary Exposure and Risks

Occupational and residential exposure to atrazine, simazine and cyanazine varies depending on several factors including the use pattern, the specific crop treated, the personal protective equipment used, whether the person exposed is a grower or commercial applicator, whether an individual is mixing, loading or applying the pesticide, and whether the individual is a homeowner. In general, a grower is likely to be involved in all aspects of the pesticide treatment, while in commercial operations, different individuals usually mix/load and apply the pesticide. The total exposure to growers is generally lower than for commercial operators because growers usually treat fewer acres, use less pounds of active ingredient per season and are exposed for only a few days each year. The Agency has estimated only dermal exposure to workers and residents because inhalation exposure for the triazines is negligible in comparison to dermal exposure.

A. Triazine Non-Dietary Exposure and Carcinogenicity Risk

1. *Exposure assumptions*— a. *Atrazine.* The Agency has estimated exposure for mixer/loaders; aerial, ground boom and handheld spray gun applicators; and aerial flaggers at representative use sites. The use sites chosen because they represent major atrazine uses are corn, sorghum and sugarcane. Macadamia nut orchards are selected to represent handheld spray gun applications and turf uses are selected to represent home gardener uses.

In determining the exposure estimates for the representative atrazine use sites, it is assumed that all pesticide handlers wear long sleeve shirts, long pants and boots, but only mixer/loaders wear chemical resistant gloves. Exposure to mixer/loaders is estimated assuming an open pour system or a closed loading system. For ground boom application to corn, sorghum and sugarcane, exposure to applicators using an open cab is distinguished from that of applicators using closed cab equipment; however, currently registered labels do not require closed loading nor closed cab tractors. Atrazine exposure estimates for agricultural crops were derived using an application rate of 1.0 or 1.2 lbs. active ingredient/acre.

The Agency has considered a recent exposure study submitted by Ciba that monitored dermal and inhalation exposure to mixer/loaders and applicators during commercial and homeowner turf treatment using products containing atrazine. This exposure monitoring study characterized exposure for four different scenarios, including: (1) home use lawn treatment using a "Push Cyclone Spreader"; (2) home use lawn treatment with a hand cyclone spreader; (3) mixing/loading and "handgun" application to client lawns by a pest control operator (PCO); and (4) mixing/loading and "handgun" spray application to a golf course by a golf course caretaker. To estimate exposure to homeowners and PCO/golf course caretakers, application rates of 3.17 and 3.96 lbs. active ingredient/acre, respectively, were used.

b. *Simazine.* Dermal exposure estimates for agricultural workers exposed to simazine are based on the same assumptions as those discussed above for atrazine. Exposure estimates from open or closed loading systems,

open or closed cab tractors, or from use of aerial equipment are used to estimate the cancer risk from occupational exposure. Simazine estimates are based on an application rate of 1.1 lb. active ingredient/acre.

c. *Cyanazine.* The Agency has derived exposure estimates for corn, the predominant cyanazine use site. These estimates are based on assessments completed for atrazine because both pesticides are used and applied to field corn in a similar fashion. The cyanazine estimates are based on an application rate of cyanazine alone at 3 lb. active ingredient/acre.

2. *Non-dietary cancer risk estimates.* Excess individual lifetime cancer risk estimates for agricultural workers are calculated from the following equation:

Cancer risk = Q_1^* × LADE × percent dermal absorption where LADE = exposurex (mg/kg/yr)/365 days/yr × 35/70 = lifetime average daily exposure.

For home use and commercial application to turf, the cancer risks are estimated from the following equation:

Cancer risk = Q_1^* × LADD (lifetime average daily dose) where LADD = (Dermal LADE × percent dermal absorption) + Inhalation LADE

a. *Atrazine.* To estimate cancer risk for atrazine, the Agency used a dermal absorption value of 26.9 percent derived from a rat dermal absorption study. Based on this dermal absorption value, upper bound excess individual lifetime cancer risks range from 10^{-6} to 10^{-2} for individuals involved in the agricultural application of atrazine as shown in Table 7 (Ref. 64):

TABLE 7.— ATRAZINE - OCCUPATIONAL CANCER RISK ESTIMATES FOR AGRICULTURAL CROPS

Crop/Application Method	Tasks	Daily Exposure (mg/kg/day)	Annual Exposure (mg/kg/yr)	Upper Bound Cancer Risk Estimates[1]
Corn - Grower/Ground boom[2]	M/L - open	1.78	3.11	2.5×10^{-4}
	M/L - closed	0.029	0.05	4.0×10^{-6}
	A - open	4.96	8.65	7.1×10^{-4}
	A - closed	0.19	0.34	2.8×10^{-5}
	M/L/A - open/open	6.74	11.76	9.5×10^{-4}
	M/L/A - open/closed	1.97	3.45	2.8×10^{-4}
	M/L/A - closed/open	4.99	8.70	7.1×10^{-4}
	M/L/A -closed/closed	0.22	0.39	3.1×10^{-5}
Corn - Commercial/Ground boom	M/L - open	6.38	95.66	7.7×10^{-3}
	M/L - closed	0.10	1.54	1.2×10^{-4}
	A - open	5.15	77.76	6.5×10^{-3}
	A - closed	0.20	3.02	2.4×10^{-4}
	M/L/A - open/open	11.53	173.42	1.4×10^{-2}
	M/L/A - open/closed	6.58	98.68	8.3×10^{-3}
	M/L/A - closed/open	5.25	79.30	6.5×10^{-3}
	M/L/A -closed/closed	0.30	4.56	3.7×10^{-4}
Corn - Commercial/Aerial	M/L - closed	0.099	1.49	1.2×10^{-4}
	Pilot	0.008	0.12	9.5×10^{-6}
	Flagger	0.044	0.66	5.3×10^{-5}
Sorghum - Grower/Ground boom [2]	M/L - open	1.42	1.79	1.5×10^{-4}
	M/L - closed	0.023	0.029	2.4×10^{-6}
	A - open	4.8	5.99	4.9×10^{-4}
	A - closed	0.19	0.23	1.9×10^{-5}
	M/L/A - open/open	6.22	7.78	6.5×10^{-4}
	M/L/A - open/closed	1.61	2.02	1.7×10^{-4}
	M/L/A - closed/open	4.82	6.02	4.9×10^{-4}
	M/L/A - closed/closed	0.21	0.26	2.1×10^{-5}
Sugarcane - Ground boom (Commercial)	M/L - open	5.31	80.0	6.5×10^{-3}
	M/L - closed	0.086	1.3	1.1×10^{-4}
	A - open	4.29	64.2	5.2×10^{-3}
	A - closed	0.17	2.49	2.0×10^{-4}
	M/L/A - open/open	9.60	144.2	1.2×10^{-2}
	M/L/A - open/closed	5.48	82.49	6.5×10^{-3}
	M/L/A - closed/open	4.38	65.5	5.3×10^{-3}
	M/L/A -closed/closed	0.26	3.79	3.1×10^{-4}
Sugarcane - Aerial	M/L - closed	0.094	2.8	2.2×10^{-4}

TABLE 7.— ATRAZINE - OCCUPATIONAL CANCER RISK ESTIMATES FOR AGRICULTURAL CROPS—Continued

Crop/Application Method	Tasks	Daily Exposure (mg/kg/day)	Annual Exposure (mg/kg/yr)	Upper Bound Cancer Risk Estimates[1]
Macadamia nuts - Handheld sprayer[2]	Pilot	0.007	0.22	1.8×10^{-5}
	Flagger	0.041	1.23	1.0×10^{-4}
	M/L - open	0.79	3.2	2.6×10^{-4}
	A - single applicator	16.84	67.4	5.4×10^{-3}
	A - split application	16.84	33.7	2.7×10^{-3}
	M/L/A - single app.	17.63	70.6	5.7×10^{-3}
	M/L/A - split app.	17.63	36.9	3.0×10^{-3}

[1] Based on potential dermal absorption of 26.9%.
[2] Exposure is only 1 to 4 days per year.

Because growers are likely to be involved in mixing, loading and applying atrazine, it is important to consider the total exposure from all of these operations. In commercial operations, different individuals are likely to mix/load and apply atrazine. The occupational cancer risk estimates for atrazine are primarily dependent upon whether mixer/loaders use open versus closed loading systems, and whether application occurs from open versus closed cab equipment. As stated previously, currently approved labels do not require closed equipment. In addition, cancer risk estimates vary depending on the method of application.

The Agency estimates the upper bound excess individual lifetime cancer risks for residents loading and applying atrazine to home lawns to range from 10^{-6} to 10^{-5}. For PCO treatment of turf, cancer risk estimates are in the range of 10^{-3} for mixer/loaders, applicators and mixer/loader/applicators. The cancer risk estimates for treatment of golf courses by golf course caretakers are 10^{-5} for both mixer/loaders and applicators, while the cancer risk to those performing all three tasks is 10^{-4}. These estimates are shown in Table 8 (Ref. 65):

TABLE 8.— ATRAZINE - OCCUPATIONAL CANCER RISK ESTIMATES FOR TURF/LAWNS

Application Method	Tasks	Daily Dermal Exposure[1] (mg/kg/day)	Daily Inhalation Exposure[1] (mg/kg/day)	Annual Dermal Exposure[1] (mg/kg/yr)	Annual Inhalation Exposure[1] (mg/kg/yr)	Upper Bound Cancer Risk Estimates[2]
Home Use - Push Cyclone Spreader[3].	M/L/A	0.045	0.0002	0.045	0.0002	3.7×10^{-6}
Home Use - Hand Cyclone Spreader[3].	M/L/A	0.285	0.0008	0.285	0.0008	2.4×10^{-5}
PCO - Handgun Application	M/L	0.217	0.016	11.593	0.878	1.2×10^{-3}
	A	0.282	0.004	15.106	0.211	1.3×10^{-3}
	M/L/A	0.499	0.020	26.699	1.088	2.5×10^{-3}
Golf Course - Handgun Application.	M/L	0.739	0.056	0.739	0.056	7.7×10^{-5}
	A	1.702	0.069	1.702	0.069	1.6×10^{-4}
	M/L/A	8.311	0.336	8.311	0.336	7.8×10^{-4}

[1] Assumes 70 kg worker.
[2] Based on potential dermal absorption of 26.9% and potential inhalation absorption of 100%.
[3] Gloves were not worn.

b. *Simazine.* To estimate cancer risk for simazine, the Agency used a dermal absorption value of 32 percent derived from a rat dermal absorption study. Based on this dermal absorption value, estimated upper bound cancer risks to individuals involved in the application of simazine to field corn range from 10^{-6} to 10^{-2} (Ref. 64). Occupational cancer risks are comparable to those of atrazine because both pesticides are applied using similar equipment and application rates. The occupational cancer risks from exposure to simazine are provided in Table 9:

TABLE 9.—SIMAZINE - OCCUPATIONAL CANCER RISK ESTIMATES

Crop/Application Method	Tasks	Daily Exposure (mg/kg/day)	Annual Exposure (mg/kg/yr)	Upper Bound Cancer Risk Estimates[1]
Corn - Grower/Ground boom	M/L - open	1.61	2.86	1.5×10^{-4}
	M/L - closed	0.026	0.046	2.4×10^{-6}
	A - open	4.54	7.93	4.2×10^{-4}
	A - closed	0.18	0.31	1.6×10^{-5}
	M/L/A - open/open	6.15	10.79	5.8×10^{-4}
	M/L/A - open/closed	1.79	3.17	1.7×10^{-4}
	M/L/A - closed/open	4.57	7.98	4.2×10^{-4}

TABLE 9.—SIMAZINE - OCCUPATIONAL CANCER RISK ESTIMATES—Continued

Crop/Application Method	Tasks	Daily Exposure (mg/kg/day)	Annual Exposure (mg/kg/yr)	Upper Bound Cancer Risk Estimates[1]
	M/L/A - closed/closed	0.21	0.36	1.9×10^{-5}
Corn - Commercial/Ground boom	M/L - open	5.85	87.7	4.6×10^{-3}
	M/L - closed	0.094	1.41	7.3×10^{-5}
	A - open	4.72	71.3	3.8×10^{-3}
	A - closed	0.18	2.77	1.5×10^{-4}
	M/L/A - open/open	10.57	159.0	8.4×10^{-3}
	M/L/A - open/closed	6.03	90.47	4.6×10^{-3}
	M/L/A - closed/open	4.81	72.71	3.8×10^{-3}
	M/L/A - closed/closed	0.27	4.18	2.2×10^{-4}
Corn - Commercial/Aerial	M/L - closed	0.091	1.36	7.3×10^{-5}
	Pilot	0.007	0.11	5.8×10^{-6}
	Flagger	0.04	0.60	3.1×10^{-5}

[1] Based on potential dermal absorption of 32%.

c. *Cyanazine.* To estimate cancer risk for cyanazine, the Agency used a dermal absorption value of 2 percent derived from a rat dermal absorption study. Based on this dermal absorption value, the occupational cancer risks to individuals involved in the application of cyanazine to field corn range from 10^{-6} to 10^{-2} (Ref. 64). The results are comparable to those of atrazine and simazine and are provided in Table 10:

TABLE 10.—CYANAZINE - OCCUPATIONAL CANCER RISK ESTIMATES

Crop/Application Method	Tasks	Daily Exposure mg/kg/day)	Annual Exposure (mg/kg/yr)	Upper Bound Cancer Risk Estimates[1]
Corn - Grower/Ground boom	M/L - open	4.46	7.77	2.2×10^{-4}
	M/L - closed	0.072	0.13	3.6×10^{-6}
	A - open	12.39	21.63	6.0×10^{-4}
	A - closed	0.48	0.84	2.4×10^{-5}
	M/L/A - open/open	16.85	29.40	8.0×10^{-4}
	M/L/A - open/closed	4.94	8.61	2.4×10^{-4}
	M/L/A - closed/open	12.46	21.76	6.0×10^{-4}
	M/L/A - closed/closed	0.55	0.97	2.6×10^{-5}
Corn - Commercial/Ground boom	M/L - open	15.94	239.1	6.6×10^{-3}
	M/L - closed	0.26	3.86	1.1×10^{-4}
	A - open	12.88	194.4	5.4×10^{-3}
	A - closed	0.50	7.54	2.0×10^{-4}
	M/L/A - open/open	28.82	433.50	1.2×10^{-2}
	M/L/A - open/closed	16.44	246.64	6.8×10^{-3}
	M/L/A - closed/open	13.14	198.26	5.4×10^{-3}
	M/L/A - closed/closed	0.76	11.40	3.2×10^{-4}
Corn - Commercial/Aerial	M/L - closed	0.25	3.71	1.0×10^{-4}
	Pilot	0.02	0.30	8.2×10^{-6}
	Flagger	0.11	1.65	4.6×10^{-5}

[1] Based on potential dermal absorption of 2%.

B. Triazine Non-Dietary Exposure and Cardiotoxicity Risks (Atrazine Only)

1. *Cardiotoxicity risk exposure assumptions.* As discussed in Unit III of this notice, the Agency used a NOEL of 5.0 mg/kg/day to characterize cardiotoxicity risk to workers from exposure to atrazine. Because this NOEL was derived from an oral feeding study, and the primary route of exposure to workers is via dermal contact, the Agency accommodated for this difference by using kinetic data which allowed a comparison of peak blood concentration data from oral toxicity and dermal absorption studies (Ref. 66). Comparing the blood concentrations following administration by different routes represents a more accurate method of assessing exposure and ultimately risk because it accounts for absorption, distribution and excretion, which can be different depending upon the route of administration. The data showed that maximum blood levels following dermal exposure were several orders of magnitude lower than those following ingestion of the chemical at similar doses.

2. *Margins of exposure (MOE) for cardiotoxic risk.* The Agency generally considers an MOE of 100 or greater to be adequately protective for workers. The Agency calculated MOE values by comparing daily exposure estimates against a NOEL of 5.0 mg/kg/day for cardiotoxicity. Using the revised NOEL of 5.0 mg/kg/day and the kinetic data, the MOEs for workers functioning as mixer/loaders and applicators are

greater than 100 for all use scenarios, thereby alleviating the Agency's concerns of cardiotoxic effects for workers exposed to atrazine (Ref. 65).

IX. Combining Cancer Risks Across Exposure Pathways and Chemicals

In June, 1993, the National Academy of Sciences released a report entitled "Pesticides in the Diets of Infants and Children." The report, requested in 1988 by the U.S. Congress, made specific recommendations for changes in pesticides regulatory practice, including the area of risk assessment methodology. The Academy recommended that EPA evaluate potential risk from exposure to several pesticides with common mechanisms of action and/or exposure via multiple routes. These recommendations are, in fact, long standing directives of the law governing the tolerance setting process, as set forth in the Federal Food, Drug and Cosmetic Act. Section 408 of the Act specifically states that appropriate consideration is to be given "...to other ways in which a consumer might be affected by the same pesticide chemical or by related substances that are poisonous or deleterious..." The Agency is implementing these recommendations using a phased-in approach, beginning with a few case studies for which information already exists to establish a commonality of mechanism. For assessments involving multiple routes of exposure, case studies will also be conducted. These studies will evaluate potential cumulative exposures resulting from a single chemical which has many food uses as well as domestic and commercial non-food uses. An example of the ultimate implementation of these recommendations would be a case study for a chemical class which appears to share a commonality of mechanism of action and is registered for use on many food, nonfood and residential sites. In the coming years, substantial discussion, research and generation of data will be needed to reach agreement both on what is meant by "common mechanisms of action" and appropriate methods for estimating risks to subpopulations from multiple routes of exposure.

The Agency has selected the triazines as a candidate for one of the case studies. This selection was based on a number of factors. This group of pesticides presents an example where a plausible argument can be made for supporting the assumption that atrazine, simazine and cyanazine operate through a common mechanism of action for the carcinogenic response observed in the rat mammary gland. In addition, treatment of various commodities with atrazine, simazine and cyanazine results in the presence of common metabolites, some of which are of toxicological significance. From an exposure standpoint, the triazines are used on a variety of food and non-food sites, both in an occupational and residential setting. Additionally, the potential exists for exposure through consumption of contaminated ground and surface water. Therefore, the triazines present an example where the Agency can address pesticides with commonality of mechanism as well as exposure through multiple pathways.

The Agency believes the triazines case study presents an opportunity for public participation in the development of improved risk assessment methodologies. The Agency acknowledges that there are several ways of approaching this problem and the triazines case study presents but one way. Moreover, the Agency welcomes input from interested parties on this approach and sees this as an initial step in implementing the Academy's recommendations.

A. Combining Estimated Cancer Risks Across Exposure Pathways

In the past, for the most part, the Agency has evaluated the human health risks for various exposure pathways separately and has not combined these risk estimates to obtain a composite risk estimate for a single pesticide. In reality, individuals may be routinely exposed to a given pesticide through several exposure pathways. For the triazine herbicides, potential exposure pathways include consumption of residues in food, consumption of contaminated drinking water, application to agricultural commodities by both growers and commercial operators, application around the home and post-application exposure. Rather than quantifying exposure for every possible use, the Agency normally focuses on the primary uses and those likely to result in the highest exposure. This step has been performed for the triazines, with exposure and upper bound excess individual lifetime cancer risk estimates contained in Tables 1 through 3 and Tables 5 through 10 of this notice.

After identifying all possible exposure pathways, the next step is to identify reasonable exposure pathway combinations that have the potential to expose the same individual or subpopulation. For example, drinking water may only be contaminated in a localized portion of the country and it would be inappropriate to assume the entire population of the United States is exposed via this pathway. It is also useful to estimate the number of individuals potentially exposed via each pathway. In determining whether it is reasonable to combine exposure pathways, the temporal relationship of those exposures is relatively unimportant as long as exposure levels are low because the multistage model for carcinogens predicts additivity at low levels of exposure. In other words, each additional exposure increases an individual's cancer risk incrementally, if one is assuming a multistage model of carcinogenesis. The possible combination of exposure pathways can be extremely complex for pesticides with many uses, such as the triazine herbicides. Some individuals or subpopulations will be exposed through several pathways while others may be exposed via a single pathway (e.g., dietary only). One approach is to develop a matrix of reasonable exposure combinations for each triazine herbicide, with each combination depicting exposure to a subset of the overall population. However, as a first step, the excess individual lifetime cancer risks should be provided for each exposure pathway and also assuming exposure via all reasonable pathways. The remaining exposure pathway combinations will fall within this range. In many instances, one pathway will contribute the majority of exposure, with the other pathways adding a negligible amount to the overall exposure and risk. One possible combination of exposure pathways for the triazines is outlined in the following Table 11:

TABLE 11.—TRIAZINES - UPPER BOUND CANCER RISK ESTIMATES ACROSS SEVERAL EXPOSURE PATHWAYS

Exposure Pathway	Atrazine	Simazine	Cyanazine
Dietary	4.4×10^{-5}	1.1×10^{-5}	2.9×10^{-5}
Drinking Water[1]	4.2×10^{-6}	6.2×10^{-7}	9.7×10^{-6}
Occupational[2]	7.7×10^{-3}	4.6×10^{-3}	6.6×10^{-3}

TABLE 11.—TRIAZINES - UPPER BOUND CANCER RISK ESTIMATES ACROSS SEVERAL EXPOSURE PATHWAYS—Continued

Exposure Pathway	Atrazine	Simazine	Cyanazine
Residential[3]	2.4×10^{-5}	N/A	N/A
Total	7.8×10^{-3}	4.6×10^{-3}	6.6×10^{-3}

[1] Derived from surface water.
[2] Commercial application to corn using ground boom equipment-mixer/loader.
[3] Lawn treatment by homeowner using hand cyclone spreader

Accounting for other exposure pathways, such as post-application exposure, would increase the risk estimates for each pesticide. This example applies to an individual who consumes contaminated drinking water from a surface water source only, is employed as a commercial operator, and applies an atrazine product to their lawn. The number of individuals who are exposed via any combination of pathways likely will be less than for each pathway by itself. The results of the analysis indicate that one exposure pathway "drives" the overall risk when combining exposure across several pathways. This result will routinely occur when estimating cancer risks to those involved in the commercial application of these triazine pesticides.

B. Combining Cancer Risks Across Chemicals

Individuals are routinely exposed to more than one pesticide simultaneously in a given day, use season and/or year, either through dietary or occupational/residential routes of exposure. For example, individuals often apply pesticides which are tank-mixed or pre-packaged with other active ingredients. Moreover, multiple chemical exposures from foods may occur through consumption of a single commodity with multiple pesticide residues and/or consumption of multiple commodities with single or multiple pesticide residues. However, EPA risk assessments have traditionally focussed on exposure from a single pesticide which may underestimate risks in many instances. The Academy highlighted this issue by recommending that EPA combine exposures of pesticides with common mechanisms of action. The Agency's Risk Assessment Guidelines for Chemical Mixtures, published in 1986, provide useful guidance for assessing the overall potential for cancer and noncancer effects posed by multiple chemicals. These guidelines can also be applied to the case of simultaneous exposures to several chemicals from a variety of sources and by more than one exposure pathway. The Agency is currently in the process of revising these guidelines.

The Agency's Risk Assessment Guidelines for Chemical Mixtures do not recommend a single approach to assess risks from multiple chemical exposures. Rather, the Guidelines outline a risk assessment approach based on the quality of the toxicity database. The ideal approach for assessing risks from chemical mixtures is to obtain toxicological data on the mixture itself. However, as is the case with most chemical mixtures, very little if any toxicity data are available for pesticide mixtures. Some data are available on pesticide products containing mixtures, but these data are usually limited to acute toxicity data and are not useful for assessing subchronic and chronic risks or, even acute risk, in general. Fortunately, a wealth of toxicity data is available on single active ingredients or the various components of a pesticide mixture. In the absence of data on the potential interaction among the components, the Guidelines for Chemical Mixtures recommend additive models for risk assessment of chemical mixtures. This is a default assumption that assumes independence of action by the pesticides involved (i.e., that there are not synergistic or antagonistic chemical interactions and that all chemicals produce the same effect). The Guidelines state further that "...Based on current information, additivity assumptions are expected to yield generally neutral risk estimates (i.e., neither conservative nor lenient) and are plausible for component compounds that induce similar types of effects at the same sites of action."

The Guidelines state that for carcinogens where linearity of the individual carcinogenic dose-response relationships has been assumed, it is appropriate to simply sum excess individual lifetime cancer risks to account for exposure to several compounds. This approach assumes independence of action and additivity among the several carcinogens. For pesticides, summing excess cancer risks is relevant for both product mixtures and situations where an individual may be exposed to several pesticides, as long as exposures are small.

In the case of the triazines, a plausible argument can be made for supporting the assumption that atrazine, simazine and cyanazine operate through a common mechanism of action in inducing mammary tumors in the rat. Of the currently registered triazine herbicides, these three pesticides are all members of the 2-chloro-4,6-bis-(alkylamino)-*s*-triazine subgroup. They also produce the same tumor type - malignant mammary gland tumors in the Sprague-Dawley rat. The Agency conducted a Structure Activity Relationship Analysis concluding that this subgroup of triazines poses a hazard of equal concern, both qualitatively and quantitatively, when compared with one another. The Agency has assumed additivity and that no synergistic or antagonistic interaction between these three chemicals exists, which is consistent with the Guidelines on Chemical Mixtures when chemical-specific data do not exist or contradict this assumption. Therefore, the Agency used a simple additive approach to estimate lifetime excess cancer risks for concurrent and sequential exposure to atrazine, simazine and cyanazine.

Each exposure pathway discussed earlier in this notice has been addressed for atrazine, simazine and cyanazine. Additional exposure pathways do exist (e.g., post-application exposure) which the Agency may evaluate in the future. The dietary risk estimates for each commodity and a total across all commodities, characterize the total dietary risk from commodities treated with atrazine, simazine and cyanazine as provided in Table 12:

TABLE 12.—TOTAL DIETARY CANCER RISK ESTIMATES - TRIAZINES

Commodity	Atrazine	Simazine	Cyanazine	Total
Almonds	0	1.5×10^{-8}	0	1.5×10^{-8}
Apples	0	1.9×10^{-6}	0	1.9×10^{-6}
Avocados	0	2.3×10^{-8}	0	2.3×10^{-8}
Bananas/Plantains	0	5.6×10^{-8}	0	5.6×10^{-8}
Blueberries	0	5.4×10^{-8}	0	5.4×10^{-8}
Caneberries	0	8.6×10^{-8}	0	8.6×10^{-8}
Cherries	0	2.0×10^{-7}	0	2.0×10^{-7}
Corn, sweet	3.1×10^{-6}	1.4×10^{-7}	5.7×10^{-6}	8.9×10^{-6}
Corn, other	5.2×10^{-6}	8.2×10^{-8}	6.2×10^{-6}	1.1×10^{-5}
Cottonseed	0	0	9.3×10^{-8}	9.3×10^{-8}
Cranberries	0	2.0×10^{-7}	0	2.0×10^{-7}
Currants	0	3.2×10^{-9}	0	3.2×10^{-9}
Eggs	1.3×10^{-6}	2.1×10^{-8}	1.7×10^{-6}	3.0×10^{-6}
Filberts	0	4.8×10^{-9}	0	4.8×10^{-9}
Grapefruit	0	6.2×10^{-7}	0	6.2×10^{-7}
Grapes	0	4.7×10^{-7}	0	4.7×10^{-7}
Guava	0	0	0	0
Lemons	0	1.2×10^{-7}	0	1.2×10^{-7}
Macadamia nuts	6.6×10^{-10}	6.0×10^{-10}	0	1.3×10^{-9}
Milk	9.3×10^{-6}	8.9×10^{-8}	1.2×10^{-6}	1.1×10^{-5}
Millet	0	0	0	0
Olives	0	1.2×10^{-8}	0	1.2×10^{-8}
Oranges	0	5.7×10^{-6}	0	5.7×10^{-6}
Peaches	0	4.5×10^{-7}	0	4.5×10^{-7}
Pears	0	3.7×10^{-7}	0	3.7×10^{-7}
Pecans	0	5.8×10^{-9}	0	5.8×10^{-9}
Pineapple	9.0×10^{-8}	0	0	9.0×10^{-8}
Plums	0	8.9×10^{-8}	0	8.9×10^{-8}
Poultry meat	6.8×10^{-8}	1.8×10^{-8}	1.3×10^{-6}	1.4×10^{-6}
Red meat	2.1×10^{-6}	2.8×10^{-8}	1.0×10^{-5}	1.2×10^{-5}
Sorghum	4.8×10^{-7}	0	1.2×10^{-7}	6.0×10^{-7}
Strawberries	0	2.1×10^{-7}	0	2.1×10^{-7}
Sugarcane	2.2×10^{-5}	0	0	2.2×10^{-5}
Walnuts	0	2.9×10^{-8}	0	2.9×10^{-8}
Wheat	6.2×10^{-8}	0	2.3×10^{-6}	2.4×10^{-6}
Total (Best Available Data)	4.4×10^{-5}	1.1×10^{-5}	2.9×10^{-5}	8.4×10^{-5}

The excess individual lifetime cancer risks from consuming contaminated drinking water can also be combined for atrazine, simazine and cyanazine. These estimates were derived assuming that individuals would consume contaminated water entirely from either ground or surface water sources for a lifetime of 70 years. In addition, the drinking water risk estimates are only applicable to the population residing in the corn belt region of the United States, or a subset of that population. For example, approximately 29 million people rely on surface water for their drinking water in 11 major corn-producing states, but the actual population consuming contaminated water is unknown at this time. The combined cancer risks estimated from exposure to drinking water

contaminated with atrazine, simazine and cyanazine are provided in Table 13:

TABLE 13.— TRIAZINES - TOTAL DRINKING WATER CANCER RISK ESTIMATES

Exposure Pathway	Atrazine	Simazine	Cyanazine	Total
Ground Water	9.9×10^{-7}	8.1×10^{-8}	2.3×10^{-6}	3.4×10^{-6}
Surface Water	4.2×10^{-6}	6.2×10^{-7}	9.7×10^{-6}	1.5×10^{-5}

Individuals are also exposed to the triazines during application to agricultural commodities. The occupational cancer risk estimates in Tables 7, 9 and 10 are based on the assumption that atrazine, simazine and cyanazine are applied in single active ingredient products; however, the triazines are routinely applied in combination either as pre-packaged products or as tank-mixes. The application rate tends to be reduced for each component triazine when applied in combination as compared to the rate of single active ingredient products. It is also possible that more than one triazine may be applied alone to a crop at different times during the use season. The magnitude of exposure will also depend upon whether the individual handling of the triazines is done by a private grower or commercial operator. Growers may have several different commodities that require triazines treatment at varying rates and combinations (i.e., sorghum and field corn). In the case of commercial operators, they are likely to treat several crops and use all three triazines within a given locality. Commercial operators will also be exposed to a greater extent because they treat more acres and handle more pounds of active ingredient than growers, in most instances.

As with the dietary example discussed above, estimated occupational cancer risks from multiple triazine exposure can be added for each commodity separately, as well as across several commodities. The various combinations of exposure scenarios can be represented by a complex matrix. A simple example is outlined below focusing on field corn because it is the only site where the Agency has estimated excess cancer risks for workers handling all three triazines. In addition, field corn represents the primary use site and therefore will encompass a majority of workers handling the triazines. The following Table 14 contains cancer risk estimates for private growers and commercial operators using ground boom equipment to apply the triazines in single active ingredient products and in combination with another.

TABLE 14.—CANCER RISK ESTIMATES FOR GROUND BOOM APPLICATION TO FIELD CORN

Tasks	Atrazine Alone[1]	Simazine Alone[2]	Cyanazine Alone[3]	Atrazine plus Simazine[4]	Atrazine plus Cyanazine[5]
M/L - grower	2.5×10^{-4}	1.5×10^{-4}	2.2×10^{-4}	4.1×10^{-4}	3.0×10^{-4}
A - grower	7.1×10^{-4}	4.2×10^{-4}	6.0×10^{-4}	1.2×10^{-3}	8.3×10^{-4}
M/L/A - grower	9.5×10^{-4}	5.8×10^{-4}	8.0×10^{-4}	1.6×10^{-3}	1.1×10^{-3}
M/L - commercial	7.7×10^{-3}	4.6×10^{-3}	6.6×10^{-3}	1.3×10^{-2}	1.0×10^{-2}
A - commercial	6.5×10^{-3}	3.8×10^{-3}	5.4×10^{-3}	1.1×10^{-2}	7.6×10^{-3}

[1] Application rate of 1.2 lb a.i./acre.
[2] Application rate of 1.1 lb a.i./ acre.
[3] Application rate of 3.0 lb a.i./ acre.
[4] Atrazine applied at 1.0 lb a.i./acre with 1.5 lb a.i./acre of simazine.
[5] Atrazine applied at 0.9 lb a.i./acre with 1.5 lb a.i./acre of cyanazine.

Similar considerations must be addressed for residential exposure scenarios. However, at this time, the Agency has estimated only the excess cancer risk associated with homeowner treatment of lawns with atrazine. Therefore, the question of residential exposure to multiple triazines will be evaluated in the future.

C. Combining Risks Across Multiple Pathways and Chemicals

Excess cancer risks can be added to account for multiple exposure pathways for a single triazine herbicide as well as to account for exposure to several triazines via a single exposure pathway. The next step is to account for exposure from multiple pathways and from all triazines under consideration. In other words, this will define an overall estimated risk to individuals exposed to atrazine, simazine and cyanazine via several exposure pathways. Excess individual lifetime cancer risks can be estimated for each commodity or for specific subpopulations exposed to the triazines. This matrix of possible combinations is extremely complex with a simple example outlined in Table 15:

TABLE 15.—TOTAL CANCER RISKS ACROSS SEVERAL EXPOSURE PATHWAYS AND TRIAZINES

Exposure Pathway	Atrazine	Simazine	Cyanazine	TOTAL
Dietary	4.4×10^{-5}	1.1×10^{-5}	2.9×10^{-5}	8.4×10^{-5}
Drinking Water[1]	4.2×10^{-6}	6.2×10^{-7}	9.7×10^{-6}	1.5×10^{-5}
Occupational[2,3]	1.1×10^{-3}	N/A	N/A	1.1×10^{-3}

TABLE 15.—TOTAL CANCER RISKS ACROSS SEVERAL EXPOSURE PATHWAYS AND TRIAZINES—Continued

Exposure Pathway	Atrazine	Simazine	Cyanazine	TOTAL
Residential[4]	2.4×10^{-5}	N/A	N/A	2.4×10^{-5}
TOTAL	1.2×10^{-3}	1.2×10^{-5}	3.9×10^{-5}	1.2×10^{-3}

[1] Derived from surface water.
[2] Private grower application to corn using ground boom equipment-mixer/loader/applicator.
[3] Application of a combination of atrazine and cyanazine.
[4] Lawn treatment by homeowner using hand cyclone spreader.

The excess individual lifetime cancer risk for this sample combination is 1.2×10^{-3}. This risk estimate only applies to those individuals living in the corn belt region, who are private growers and who apply an atrazine product to their lawn. Various combinations can be derived from this table with the number of exposed individuals varying as well. For example, the excess cancer risk for a typical resident in the corn belt region, uses atrazine on their lawn is 7.2×10^{-5}.

The Agency reiterates that the triazines case study presents but one approach in instituting the Academy's risk assessment recommendations. Once again, EPA invites all interested parties to comment on these initial attempts.

X. Triazine Ecological Risk

Over the past 25 years, substantial scientific literature has been generated in the United States and abroad that analyzes the environmental effects from exposure to atrazine; three important literature reviews summarize much of this information. A review by Eisler (1989) (Ref. 67) contains 118 literature citations; a review by the Kansas Department of Health and Environment (1989) (Ref. 68) contains 54 citations; and a review by Huber (1993) (Ref. 69) contains 119 citations. These reviews along with other data available to the Agency have been used to assess the environmental risks associated with atrazine use and, because of atrazine's similarities to the other two triazines, the risks of simazine and cyanazine.

Significant gaps in knowledge of the impact of protracted use of triazines on aquatic and terrestrial ecosystem function and structure have limited the Agency's ability to perform a quantitative environmental risk assessment. However, the qualitative assessment that can be done raises serious concerns about the ecological risks of continuing to apply such massive quantities of toxic chemicals across ecosystems and watersheds.

A. Triazines in the Environment

The most notable characteristic of the triazines is the vast quantity of these chemicals used each year in agriculture. A detailed discussion of the usage of the triazines is presented in Unit XI of this notice.

The pervasiveness of the triazines in the environment is the result of their massive use combined with their mobility and persistence. Due to its mobility in the environment, it is estimated that between 0.1 and 3 percent of atrazine applied to fields is lost to the aquatic environment (Ref. 67). At the lowest rates of loss (0.1 percent) and use (64 million pounds), 64,000 pounds of atrazine pollute the Nation's water resources every year. At the higher rates of loss and use, pollution jumps to 2.4 million pounds annually. Given that the three triazines behave similarly in their mobility, the upper limits of triazine pollution of water resources approaches 3.3 million pounds annually. For example, runoff water going into the Chesapeake Bay had atrazine concentrations of up to 480 µg/L (Ref. 69). Other reports of runoff concentrations from atrazine-treated fields typically range from 27 to 69 µg/L, but concentrations of over a 1,000 µg/L have been reported in Kansas and Colorado (Ref. 67).

As discussed in Unit VI of this notice, the triazines have been found in precipitation occurring from the contamination of airborne particulates and dust. In one study, the annual atmospheric input of atrazine in rainfall to the Rhode River in Maryland was estimated at 1,016 mg/surface ha in 1977, and 97 mg/ha in 1978 (Ref. 67). Triazines are also transported by fog where the maximum reading reported was 0.82 µg/L as contrasted to a maximum for rain of 2.2 µg/L (with a mean of 0.066 µg/L) (Ref. 69).

Triazine contamination of soils occurs from intentional application to control unwanted weeds and unintentionally through atmospheric transport, runoff from treated fields, drift, irrigation and flooding with contaminated water, and by accident and improper disposal.

B. Environmental Exposure

The Agency has reviewed and evaluated 12 large scale surface water studies; the study-specific sampling characteristics and results of these data have been summarized in Table 4, Unit VI of this notice. Included in the review and evaluation were surveys carried out by the Great Lakes National Program Office of the U.S. EPA, the U.S. Geological Survey, and the Missouri River Public Water Supplies Association. These studies found triazine residues are common in water, soil, and air/rainfall samples in high triazine use areas in the United States. The Agency's major ground water findings are also summarized in Unit VI of this notice.

Monitoring data for aquatic resources show that residue levels and concentrations tend to be highest following a rainfall event shortly after application. Triazines are continuously present in surface water at concentrations that may adversely effect ecosystem structure and function. From July through April, triazine concentrations are typically below 1 µg/L. However, during peak triazine usage during May and June, triazine concentrations increase considerably. For rivers in the United States, atrazine concentrations have been found at levels up to 245 µg/L with the majority of the samples having concentrations below 10 µg/L (See Table 4, Unit VI of this notice).

C. Ecological Toxicity of the Triazines

The mode of action for triazines is to inhibit photosynthesis. This inhibition also affects processes that are indirectly dependent on photosynthesis including opening of the stomata, transpiration, ion transport, and other reactions that depend on the supply of energy. At levels between 0.1 µg/L and 25 µg/L, atrazine causes reduced photosynthesis in phytoplankton (Ref. 68). The triazines inhibit the flow of electrons which, in turn, inhibit the production of adenosine triphosphate (ATP), the major energy source for the plant. Without the production of ATP during photosynthesis, phytoplankton and other aquatic as well as semi-aquatic and terrestrial plants will be at risk. There is also evidence that atrazine can upset the phytohormone and ion

balance which may seriously disrupt overall metabolism including RNA, enzyme and other protein synthesis (Ref. 69).

Triazines are fatal to some aquatic plant species at very low concentrations. Agency guideline acute toxicity studies for aquatic plants resulted in EC_{50} values for atrazine of 22 µg/L for *Isochrysis galbana* (Ref. 70); for cyanazine, 4.8 µg/L for *Navicula pelliculosa* (Ref. 71); and for simazine, 36 µg/L for *Anabaena flos-aquae* (Ref. 72). Field monitoring studies and reviews in published literature indicate that the actual toxic concentrations of the triazines and their degradates in the environment trigger deleterious effects at much lower concentrations than predicted by the laboratory guideline studies.

Sensitive aquatic plant species, particularly phytoplankton, have been found to experience temporary, but reversible, adverse effects at atrazine concentrations of 1 to 5 µg/L (Ref. 67).

Specific examples of atrazine toxicity include the following: Wildcelery (*Vallisneria americana*), a submersed vascular plant, was clearly harmed after exposures to concentrations of 3.2 to 12 µg/L for 7 weeks (Ref. 67). At higher concentrations of 13 to 1,104 µg/L for 3 to 6 weeks, the growth of representative submerged macrophytes in the Chesapeake Bay was significantly depressed, and longer exposures were fatal (Ref. 67). Atrazine concentrations of 100 µg/L for 14 days reportedly caused permanent changes in algal community structure including decreasing density and diversity, altered species composition and reduced growth (Ref. 67).

The results of 68 experiments and studies on the effects of variations in atrazine exposure on a variety of aquatic plant species are summarized by Eisler (Ref. 67). Typically, adverse effects are observed for the more sensitive species at concentrations less than 10 µg/L, and at concentrations of 10 to 100 µg/L for other species tested.

Much of the corn belt was originally part of the Tall Grass Prairie ecosystem. Many species of mature native grasses are tolerant of atrazine, but are often susceptible as seedlings. Of eight grass species tested, the three most sensitive were adversely affected in soils containing 1.1 mg atrazine/kg. Some other species of plants such as mustard (*Brassica juncea*) were even more sensitive with germination reduced by 50 percent at soil concentrations between 0.02 and 0.11 mg atrazine/kg (Ref. 67).

Eisler also summarizes the results of 46 studies and experiments on impacts of atrazine on aquatic fauna. Typically, adverse effects are observed with atrazine concentrations in the range of 100 µg/L, and fatalities in the range of 1,000 µg/L (Ref. 67).

Huber concluded that ecotoxicological effects of atrazine on plant and animal compartments and overall ecosystem function become observable at 20 µg/L, but these effects observed are not lasting. However, he did note that ecotoxicological threshold values do vary when individual organisms are evaluated (Ref. 69).

1. *Factors affecting organisms' susceptibility to toxic effects.* The considerable variation in ecotoxicological results reported is due to a variety of factors. The rates of uptake and elimination of triazines by organisms is variable both within and between species. Toxicological effects at a given concentration within a single species can vary with life stage, nutritional status, natural stress factors and the presence of other chemicals. Within the same environment, closely related species can have very different exposure levels due to differences in behavior, food preferences or stage of development. Finally, some plant species such as maize and millet are very effective at detoxification (Ref. 69).

2. *Ecological toxicity of the triazine degradates.* The toxicity, fate and exposure of the degradates of atrazine, simazine, and cyanazine are not adequately understood. Limited information indicates that the degradates are either nontoxic or 4 to 10 times less phytotoxic than their parent compound. However, given the vast quantities of triazines that are used each year, even a small percentage of the resulting moderately toxic degradates would contribute to the cumulative impact of triazine use on the environment.

D. Ecological Risks of the Triazines

1. *Aquatic risk assessment.* There are direct adverse effects on aquatic plant life and secondary effects on aquatic animals that utilize plants for food, shelter, and breeding habitat (Refs. 67, 68, and 69). Eisler proposed criteria that established threshold concentrations above which adverse effects to aquatic life are expected. For example, Eisler suggested that atrazine concentrations below 5 µg/L were adequately protective of the most sensitive flora and concentrations less than 11 µg/L were adequately protective of most aquatic plants and animals. The risk to aquatic animals is often indirect due to a loss of food and habitat (Ref. 67). Maximum observed concentrations of atrazine and cyanazine exceeded the Agency guideline aquatic plant EC_{50} values (concentration at which 50 percent of the test population is adversely affected) for atrazine, 22 µg/L for *Isochrysis galbana* and cyanazine, 4.8 µg/L for *Navicula pelliculosa* at a substantial percentage of sites represented by the corn belt studies listed in Table 4, Unit VI of this notice. The corresponding risk quotients (expected environmental concentration/aquatic plant EC_{50}) were often substantially larger than one, the level of concern (Ref. 73). Such data suggest that atrazine and cyanazine may be exerting acute effects on sensitive plant species at a substantial number of locations throughout the corn belt.

Atrazine concentrations of 5 to 10 µg/L are not uncommon during the period of peak use, late April through early July (see Table 4, Unit VI of this notice), when biological activity in aquatic ecosystems is high. Peak concentrations in excess of 100 µg/L have been reported and according to the published literature, values greater than 11 µg/L indicate a risk to aquatic plants and animals (Refz. 67 and 69).

2. *Terrestrial risk assessment.* The risk of triazine use to terrestrial organisms and ecosystems is more difficult to assess than the risk to aquatic systems. However, spray drift combined with the widespread presence of the triazines in soil, water and atmospheric resources through the corn belt lead to the conclusion that nontarget plants are periodically exposed and may suffer some adverse affects.

3. *Ecosystem impacts.* Ecosystem health depends on a variety of factors including biomass, diversity, and energy. The long term use of the triazines may affect any one or all of these factors in a number of ways. In general, all other living organisms are dependent on plants, the cornerstone of ecosystems, for their very survival. Major reductions in plant species and total plant biomass from adverse impacts on photosynthesis can adversely affect the structure and function of the entire ecosystem. Consequently, the health of plants dictates, in part, the health of the ecosystem. Widespread and perennial use of the triazines may cause adverse impacts on photosynthetic production and biodiversity. These adverse impacts, in turn, pose a threat to aquatic and terrestrial organisms and their ecosystems.

Shifts in populations may occur as a result from exposure to triazines due to the fact that not all species are affected in the same way. Such shifts in community structure could impact on animal populations by changes in the habitat and/or the type of food or

availability of food. For example, one study did find that there was a significant reduction in nonpredatory insect populations in atrazine treated ponds and attributed the reduction to indirect affects, i.e., the loss of food and habitat (Ref. 68).

Studies indicate that aquatic macrophytes and phytoplankton exhibit different levels of sensitivity to atrazine and some populations may develop resistance under prolonged herbicide stress. Under such conditions the less sensitive species would be expected to out compete the more sensitive resulting in a shift in community structure.

While the acute toxicity data available for the triazines are important in indicating the potential for adverse effects, it is unknown what the entire range and extent of the effects of long term use of the triazines has had and will continue to have over entire watersheds and ecosystems. The Agency is concerned that such effects may be substantial.

E. Registrants' Response to Preliminary Notification Concerning Ecological Risks and Agency Comments

DuPont and Ciba responded to the Agency's preliminary notification of possible Special Review for ecological effects. Both registrants believe that the triazine herbicides do not pose unreasonable risks to ecological systems. While the Agency is not initiating a Special Review of the triazines for ecological effects at this time, it does have concerns that such risks are possible and is interested in obtaining any information that will assist in refining both aquatic and terrestrial risk assessments. Requests for such information are discussed in Unit XI of this notice.

XI. Use Profile and Request for Information on Sustainable Agriculture/IPM, Reduced Pesticide Risk and Ecological Risks

A. Use/Usage Profile

Atrazine, cyanazine and simazine are used principally as pre-emergence herbicides to prevent the successful growth of a wide spectrum of broadleaf weeds and some grassy weeds. They are sometimes used as post-emergence herbicides. They have sufficient residual activity in the soil to provide season-long control of weed pests in many cases.

The Agency estimates that 90 to 121 million pounds active ingredient of the triazines are used annually in the United States with field corn representing approximately 80 percent of the total usage and sorghum representing approximately 9 percent. Sweet corn and other sites represent the remaining 11 percent (Ref. 74). Field corn, sweet corn and sorghum are the only sites where more than one of the triazines are registered. The triazines are often used in combination with another herbicide to control grassy weeds.

1. *Atrazine.* The major uses for which atrazine is registered include corn, sorghum, sugarcane, wheat fallow, macadamia nuts, guava and warm season turf grass. In terms of total pounds used over the past 30 years, atrazine has been one of the two most widely used pesticides in the United States, the other being alachlor. However, on a per year basis, metolachlor has surpassed alachlor in recent years. The total estimated atrazine usage based on USDA, proprietary and registrant information up through 1993 is between 64 and 80 million pounds active ingredient per year; this estimate represents a decline in usage over the past few years.

Field corn represents about 85 percent of total atrazine usage, sorghum another 11 percent, and the remainder distributed among the other sites. About 60 to 70 percent of U.S. field corn and sorghum acreage is treated with atrazine on an annual basis. Recent USDA data indicate that poundage may have dropped as much as 20 percent on field corn due to a decrease in the application rate growers actually use. In general, only one application a year is made to corn. Illinois, Indiana, Iowa and Nebraska account for 50 percent of atrazine usage, but 14 other states use one million pounds or more annually. Atrazine is principally applied by ground boom application at rates not to exceed 2.5 lbs. active ingredient/acre in one calendar year.

Other crops with large percentages of total acres treated with atrazine are sugarcane (about 50 percent; especially Florida, 75 percent), sweet corn (55 percent) and guava (up to 100 percent). There is some variation in application rate for sugarcane with users in Florida making more applications than users in Texas or Louisiana. On average, two post-emergence applications are made to sugarcane annually.

To increase the scope of total weed control, atrazine is usually mixed with one or more additional pesticides. Common pre-emergence mixes for corn and sorghum are atrazine plus alachlor, atrazine plus metolachlor, and atrazine plus cyanazine plus alachlor or metolachlor. Post-emergence atrazine mixes for corn and sorghum include bentazon, dicamba and bromoxynil. Paraquat or glyphosate can be mixed with atrazine to kill existing weeds in no-till fields prior to crop emergence.

2. *Simazine.* The major uses for which simazine is registered includes a variety of fruits, nuts and citrus as well as non-crop areas. All aquatic uses for simazine were cancelled by 1994; however, some existing stocks for these uses remain. Approximately 5 to 7 million pounds active ingredient of simazine are used each year in the United States, primarily in California and Florida. Approximately 30 percent of simazine's total annual usage is on corn and it is applied to about 2 percent of the U.S. corn crop. Simazine has fairly widespread usage in fruit and nut orchards because of its broad spectrum, long term residual weed control. Application rates for simazine use on food crops range from 1 to 10 lbs active ingredient/acre and is primarily applied by ground boom, direct spray, spreaders or water treatment. Rates of up to 40 lbs active ingredient/acre are currently registered for non-crop uses.

Simazine is persistent and has restrictions for some conditions where broadleaf crops may be desired for rotation. Although simazine was the first of the triazines to be registered for use on field corn, atrazine quickly replaced it because of flexibility with regard to crop tolerance and rotational crop restrictions.

Simazine is commonly tank mixed with other chemicals. Such mixes for corn include simazine plus atrazine and probably simazine plus alachlor or metolachlor. Simazine may also be formulated with other herbicides such as atrazine, bromacil, glyphosate, paraquat dichloride, and sodium chlorate as a preharvest dessicant.

Simazine usage on non-crop sites represents about 33 percent of total U.S. simazine usage, but this represents only a small fraction of the total acres for these sites. Non-crop use rates of simazine for total vegetation control range from 4 to 40 lbs active ingredient/acre. Uses of simazine on all aquatic sites were voluntarily cancelled by the technical registrants (Ref. 75). An existing stocks provision has been established for remaining stocks use on aquatic sites that pose no risk to human health.

3. *Cyanazine.* The major uses for which cyanazine is registered include corn and cotton. Approximately 21 to 34 million pounds active ingredient are used annually, of which 95 percent is used on corn. Approximately 20 percent of the total U.S. corn acreage, primarily in Iowa, is treated with cyanazine as either the sole active ingredient or in combination with other herbicides. Cyanazine is used primarily where a

broad spectrum of weed control is desirable without the carry-over associated with many of the more persistent herbicides. Cyanazine has a somewhat different weed control spectrum than atrazine and the two are often tank mixed. It has a relatively short persistence in soil compared to atrazine and simazine and has no rotational crop restrictions. Application is principally by ground boom (99 percent), but some chemigation occurs. The typical application rate for cyanazine is approximately 2 lbs. active ingredient/acre. The maximum label application rate is 6.5 lbs. active ingredient/acre.

B. Reduced Pesticide Use Initiative and Sustainable Agriculture/IPM Alternatives; Request for Information

Sustainable agriculture, as defined in the Food, Agriculture, Conservation and Trade Act of 1990, is an "integrated system of plant and animal production practices having site-specific application that will, over the long term, satisfy human food and fiber needs; enhance environmental quality and the natural resource base upon which the agricultural economy depends; make the most efficient use of nonrenewable resources and on-farm resources and integrate, where appropriate, natural biological cycles and controls; sustain economic viability of farm operations; and enhance the quality of life for farmers and society as a whole." For the triazines, pesticide management practices which promote use reduction, application methods aimed at reducing environmental loading and weed control methods using alternatives to chemicals can help promote the idea of sustainable agriculture.

The Agency is requesting any information regarding best management practices that have been used to reduce pesticide use or usage, run-off and leaching to ground and surface water, or other environmentally protective measures taken while providing adequate weed control on sites where the triazines are registered for use. The Agency is requesting data which will compare the triazines to alternative practices that will support sustainable agriculture. Sustainable agricultural management practices may include crop rotation plans, use of buffer strips and banded application, among others. The Agency is requesting all relevant field test results that compare the performance of the triazines with that of other major pesticide alternatives. Additionally, the Agency is requesting data comparing the triazines at lower application rates and improved application methodologies to alternatives.

It is well known that populations of various weed species have developed resistance to certain herbicides, including the triazines. The Agency seeks information on the prevalence and distribution of triazine-resistant weed species, how these resistant species are controlled and the role of triazines in the general problem of resistance management.

The Agency is particularly interested in comparing the effectiveness and economic feasibility of alternative pest control methods. For instance, information obtained in trials about the yield and quality of crops grown using biological and other non-chemical weed control on commodities now treated with the triazines is of interest. Additionally, information concerning the role of triazines, other chemical herbicides and other weed control practices in Integrated Pest Management programs as well as information comparing yield, quality and profitability of such programs or other alternative crop production programs is requested.

The Agency is also interested in receiving information to develop its aquatic, terrestrial and ecosystem risk assessments. This includes the following types of information: combined triazine and triazine degradate ecotoxicity, surface and ground water monitoring information on triazine degradates, field studies for cyanazine and simazine, chronic phytotoxicity studies, synergistic and cumulative effects between the triazines and other agricultural chemicals, possible interaction of triazines with abiotic factors to evaluate antagonistic and synergistic effects and information on exposure models and data for streams and lakes for each triazine and various mixtures of the three.

In summary, the Agency is requesting all information on the suitability of other products and practices for maintaining the profitability of cropping that is obtained now by using triazines. Data should indicate profitability of alternative cropping systems, not merely relative efficacy in weed control. Especially valuable are comparative product performance tests in which yields and quality of the harvested crop are compared among various weed control chemicals and strategies.

XII. Duty to Submit Information on Adverse Effects

Registrants are required by section 6(a)(2) of FIFRA to submit any additional information regarding unreasonable adverse effects on humans or the environment. In light of this Special Review and the requirements of FIFRA section 6(a)(2), the registrants must notify EPA of the results of any studies, incident reports, and any other information on atrazine, simazine and cyanazine pesticides currently in progress to the extent specified in the section 6(a)(2) enforcement policy (44 FR 40716). Specifically, information on any adverse toxicological effects of atrazine, simazine and/or cyanazine pesticides, their impurities, metabolites, and degradation products must be submitted.

XIII. Public Comment Opportunity

All registrants and applicants for registration have been notified by certified mail of the Special Review being initiated on their triazine (atrazine, simazine and cyanazine) products. The Agency is providing a 120–day period to comment on this Notice. Comments must be submitted by March 23, 1995. The Agency invites all interested persons to submit further information concerning risks and benefits associated with the use of atrazine, simazine and cyanazine as discussed in this Notice. All interested persons are also invited to comment on whether the use of atrazine, simazine or cyanazine satisfies any of the risk criteria listed at 40 CFR 154.7, whether risks posed by the use of atrazine, simazine or cyanazine are unreasonable, and what, if any, regulatory action should be taken by the Agency.

Comments claimed as CBI must be clearly marked as "confidential," "trade secret," or other appropriated designation on the face of the comments. Comments marked as such will be treated in accordance with the procedures in 40 CFR 2.204(e)(4). Comments not claimed as confidential at the time of submission, or not clearly labeled as containing CBI, will be placed in the public docket. The Agency will consider the failure to clearly identify the claimed confidential status on the face of the comment as a waiver of such claim, and will make such information available to the public without further notice to the submitter.

All comments and information should be submitted in triplicate to the address given in this Notice under the ADDRESSES section to facilitate the work of EPA and others interested in inspecting them. The comments and information should bear the identifying notation "OPP–30000–60."

During the comment period, interested members of the public or registrants may request a meeting to discuss factual information available to the Agency, to present any factual

information, to respond to presentations by other persons, or to discuss what regulatory actions should be taken regarding the triazine herbicides. Persons interested in arranging such meetings should contact the person listed at the beginning of this Notice under "FOR FURTHER INFORMATION CONTACT."

As part of an interagency "streamlining" initiative, EPA is experimenting with submission of public comments on selected **Federal Register** actions electronically through the Internet in addition to accepting comments in traditional written form. This Notice is one of the actions selected by EPA for this experiment. From the experiment, EPA will learn how electronic commenting works, and any problems that arise can be addressed before EPA adopts electronic commenting more broadly in its rulemaking activities. Electronic commenting through posting to the EPA Bulletin Board or through the Internet using the ListServe function raise some novel issues that are discussed below in this Unit.

To submit electronic comments, persons can either "subscribe" to the Internet ListServe application or "post" comments to the EPA Bulletin Board. To "Subscribe" to the Internet ListServe application for this Notice, send an e-mail message to: listserver@unixmail.rtpnc.epa.gov that says "Subscribe OPP–30000–60 <first name> <last name>." Once you are subscribed to the ListServe, comments should be sent to: OPP–30000–60@unixmail.rtpnc.epa.gov.

For online viewing of submissions and posting of comments, the public access EPA Bulletin Board is also available by dialing 202–488–3671, enter selection "DMAIL," user name "BB—USER" or 919–541–4642, enter selection "MAIL," user name "BB—USER." When dialing the EPA Bulletin Board type <Return> at the opening message. When the "Notes" prompt appears, type "open OPP– 30000–60" to access the posted messages for this document. To get a listing of all files, type "dir/all" at the prompt line. Electronic comments can also be sent directly to EPA at:

Docket-OPPTS@epamail.epa.gov.

To obtain further information on the electronic comment process, or on submitting comments on this Notice electronically through the EPA Bulletin Board or the Internet ListServe, please contact John A. Richards (Telephone: 202–260–2253; FAX: 202–260–3884; Internet: richards.john@epamail.epa.gov).

Persons who comment on this Notice, and those who view comments electronically, should be aware that this experimental electronic commenting is administered on a completely public system. Therefore, any personal information included in comments and the electronic mail addresses of those who make comments electronically are automatically available to anyone else who views the comments. Similarly, since all electronic comments are available to all users, commenters should not submit electronically any information which they believe to be CBI. Such information should be submitted only directly to EPA in writing as described earlier in this Unit.

Commenters and others outside EPA may choose to comment on the comments submitted by others using the OPP–30000–60 ListServe or the EPA Bulletin Board. If they do so, those comments as well will become part of EPA's record for this rulemaking. Persons outside EPA wishing to discuss comments with commenters or otherwise communicate with commenters but not have those discussions or communications sent to EPA and included in the EPA rulemaking record should conduct those discussions and communications outside the OPP–30000–60 ListServe or the EPA Bulletin Board.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically in the OPP–30000–60 ListServe or the EPA Bulletin Board, in accordance with the instructions for electronic submission, into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. All the electronic comments will be available to everyone who obtains access to the OPP–30000–60 ListServe or the EPA Bulletin Board; however, the official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document. (Comments submitted only in written form will not be transferred into electronic form and thus may be accessed only by reviewing them in the Public Response and Program Resources Branch as described above.)

Because the electronic comment process is still experimental, EPA cannot guarantee that all electronic comments will be accurately converted to printed, paper form. If EPA becomes aware, in transferring an electronic comment to printed, paper form, of a problem or error that results in an obviously garbled comment, EPA will attempt to contact the comment submitter and advise the submitter to resubmit the comment either in electronic or written form. Some commenters may choose to submit identical comments in both electronic and written form to ensure accuracy. In that case, EPA requests that commenters clearly note in both the electronic and written submissions that the comments are duplicated in the other medium. This will assist EPA in processing and filing the comments in the rulemaking record.

As with ordinary written comments, at the time of receipt EPA will not attempt to verify the identities of electronic commenters nor to review the accuracy of electronic comments. Electronic and written comments will be placed in the rulemaking record without any editing or change by EPA except to the extent changes occur in the process of converting electronic comments to printed, paper form.

If it chooses to respond officially to electronic comments on this Notice, EPA will do so either in a notice in the **Federal Register** or in a response to comments document placed in the rulemaking record for this Notice. EPA will *not* respond to commenters electronically other than to seek clarification of electronic comments that may be garbled in transmission or conversion to printed, paper form as discussed above. Any communications from EPA employees to electronic commenters, other than those described in this paragraph, either through Internet or otherwise are not official responses from EPA.

XIV. Public Docket

The Agency has established a public docket [OPP–30000–60] for the triazine Special Review. This public docket will include: (1) The preliminary notification to the registrants concerning the Special Review of the triazines; (2) all written comments and materials [other than claimed confidential business information (CBI)] submitted to the Agency in response to the preliminary notification; (3) this notice; (4) any other notices pertinent to the Special Review; (5) non-CBI documents and copies of written comments or other materials submitted to the Agency in response to the pre-Special Review registrant notification, this notice, and any other Notice regarding the triazines submitted at any time during the Special Review process by any person outside government; (6) all documents or other written materials concerning the triazines Special Review provided by

the Agency to any person or party outside of government; (7) a transcript of all public meetings held by the Agency for the purpose of gathering information on the triazines; (8) memoranda describing each meeting held during the Special Review process between Agency personnel and any person outside government; and (9) a current index of materials in the public docket. On a monthly basis, the Agency will distribute a compendium of indices for newly received comments and documents that have been placed in the public docket for this Special Review. This compendium will be distributed by mail to those members of the public who have specifically requested such material for this Special Review pursuant to 40 CFR 154.15 (f)(3).

XV. References

The following list of references includes all documents cited in this notice. These documents are part of the public docket for this Special Review (Docket Number "OPP–30000–60). The Agency will continue to supplement the public docket with additional information as it is received.

The record includes the following information:

1. U.S. Environmental Protection Agency. Preliminary Notification of Special Review of Atrazine. February 8, 1994.

2. U.S. Environmental Protection Agency. Preliminary Notification of Special Review of Cyanazine. February 8, 1994.

3. U.S. Environmental Protection Agency. Preliminary Notification of Special Review of Simazine. February 8, 1994.

4. U.S. Environmental Protection Agency. Preliminary Notification of Special Review of Atrazine. August 17, 1988.

5. U.S. Environmental Protection Agency. Preliminary Notification of Special Review of Atrazine. August 24, 1989.

6. U.S. Environmental Protection Agency. **Federal Register** Notice (57 FR 29309). July 1, 1992.

7. U.S. Environmental Protection Agency. **Federal Register** Notice (59 FR 18120). Voluntary Cancellation of the Registrations of Simazine for Use in Swimming Pools, Hot Tubs and Whirlpool Baths. April 15, 1994.

8. U.S. Environmental Protection Agency. **Federal Register** Notice (59 FR 34614). Notice of Intent to Cancel the Registrations of Nuclo Dry Granular Algaecide, Nuclo Dry Algaecide 90, Winterizing Algaecide, and Algicil Plus. July 6, 1994.

9. Mayhew, D.A.; Taylor, G.D.; Smith, S.H. and Banas, D.A. Twenty-four Month Combined Chronic Oral Toxicity and Oncogenicity Study in Rats Utilizing Atrazine Technical. Conducted by American Biogenics Corporation for Ciba-Geigy Corp. Study No. 410–1102. Accession No. 262714–262727. April 29, 1986.

10. Hazelette, J.R., and Green, J.D. Atrazine Technical: 91-Week Oral Carcinogenicity Study in Mice. MRID No. 40431302. Study No. 842120. Testing Facility: Division of Toxicology/Pathology, Ciba-Geigy Corp. October 30, 1987.

11. U.S. Environmental Protection Agency. Memorandum from Judith W. Hauswirth, Office of Pesticide Programs, Health Effects Division: "Peer Review of Atrazine." June 6, 1988.

12. U.S. Environmental Protection Agency. Memorandum from Judith W. Hauswirth, Office of Pesticide Programs, Health Effects Division: "Second Peer Review of Atrazine." August 1, 1988.

13. U.S. Environmental Protection Agency. Memorandum from Marion P. Copley, Office of Pesticide Programs, Health Effects Division: "Third Peer Review of Atrazine - Reevaluation Following the September 7, 1988 Scientific Advisory Panel Review." November 22, 1988.

14. U.S. Environmental Protection Agency. Memorandum from Marion P. Copley, Office of Pesticide Programs, Health Effects Division: "Follow-up to the Third Peer Review of Atrazine." April 27, 1989.

15. U.S. Environmental Protection Agency. Memorandum from C. J. Nelson, Office of Pesticide Programs, Health Effects Division. "Atrazine - Updated Qualitative and Quantitative Risk Assessment from a Rat 2-Year Chronic Oral Toxicity/Oncogenicity Study." August 23, 1988.

16. U.S. Environmental Protection Agency. Memorandum from Marion P. Copley, Office of Pesticide Programs, Health Effects Division: "ID 0808030: Atrazine; Reevaluation of Chronic Toxicity in the 1–year Dog Study." December 19, 1989.

17. McCormick, C.C. and A.T.Arthur: "Simazine-Technical: 104–Week Oral Chronic Toxicity and Carcinogenicity Study in Rats." April 12, 1988. MRID Number: 406144–05. Study Number: 2–001109. Testing Facility: Pharmaceuticals Division, Ciba-Geigy Corp.

18. Hazelette, J.R., and Green, J.D. Simazine Technical; 95–Week Oral Toxicity/Oncogenicity Study in Mice. MRID No. 40614404. Study No. 842121. Testing Facility: Pharmaceuticals Division, Ciba-Geigy Corp. April 4, 1988.

19. Lasinski, E.; Kapaghian, J. and Green, J. Gene Mutation Test: Simazine Technical. MRID No. 40614406. Study No. 87038; 872269. Unpublished study prepared by Ciba-Geigy Corp. 1987.

20. U.S. Environmental Protection Agency. Memorandum from Esther Rinde, Office of Pesticide Programs, Health Effects Division: "Peer Review of Simazine." July 31, 1989.

21. U.S. Environmental Protection Agency. Memorandum from Bernice Fisher, Office of Pesticide Programs, Health Effects Division. "Simazine - Quantitative Risk Assessment, Two Year Chronic/Oncogenicity Sprague-Dawley Rat Study." June 5, 1989.

22. U.S. Environmental Protection Agency. Memorandum from Henry Spencer, Office of Pesticide Programs, Health Effects Division. "Peer Review of Simazine Following SAP Review." May 24, 1990.

23. Bogdanffy, M.S.: Combined chronic toxicity/oncogenicity study with cyanazine in rats. Unpublished report prepared by Haskell Laboratory and submitted by E.I. DuPont de Nemours and company. Study No. 23–90. MRID No. 415099–02. May 11, 1990.

24. U.S. Environmental Protection Agency. Memorandum from William Dykstra and George Z. Ghali, Office of Pesticide Programs, Health Effects Division. "Peer Review of Cyanazine (Bladex)." May 21, 1991.

25. Jannasch, M., V. Sawin. "Genetic Toxicity Assay of Bladex Herbicide: Gene Mutation Assay in Mammalian Cells in Culture, L5178Y, Mouse Lymphoma Cells: Project No. 61282." Unpublished study prepared by Westhollow Research Center. 1986.

26. "Determination of Unscheduled DNA Synthesis in Rat Spermatocytes following in vivo Exposure to Cyanazine by Oral Gavage." Haskell Laboratory. Study No. 281–93. April 18, 1993.

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28. U.S. Environmental Protection Agency. Memorandum from Jerome Blondell, Office of Pesticide Programs, Health Effects Division. "Italian Triazine Cancer Epidemiology Studies, HED Project No. 0–1573." September 21, 1990.

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List of Subjects

Enviromental protection, chemicals, pesticides and pest.

Dated: November 9, 1994.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

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Wednesday
November 23, 1994

Part III

Environmental Protection Agency

40 CFR Part 2, et al.
Public Information and Confidentiality Regulations; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 2, 57, 85, 86, 122, 123, 145, 233, 260, 270, 271, 281, 350, 403, 704, 707, 710, 712, 716, 717, 720, 723, 750, and 790

[FRL–4736–2]

RIN 2020–AA21

Public Information and Confidentiality Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to modify certain regulations governing the Freedom of Information Act confidential business information. This proposal makes numerous changes intended to simplify and expedite handling of confidential data.

DATES: Comments will be accepted until January 23, 1995.

ADDRESSES: Send or deliver written comments to Donald A. Sadowsky, General and Information Law Division (2379), Office of General Counsel, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Donald A. Sadowsky, Office of General Counsel. Telephone 202/260–5469.

SUPPLEMENTARY INFORMATION: On May 20, 1975 EPA published in the **Federal Register** (40 FR 21987) a proposed rule concerning procedures for the treatment of confidential business information (CBI) submitted under various environmental statutes. This final rule was published on September 1, 1976 (41 FR 36902), and codified as 40 CFR part 2, subpart B. Rules governing treatment of CBI submitted under additional environmental statutes were promulgated on September 8, 1978 (43 FR 40003), December 18, 1985 (50 FR 51663), and July 29, 1988 (53 FR 28772). EPA published additional rules concerning confidentiality on January 5, 1993 (58 FR 457) and February 5, 1993 (58 FR 7187).

The contents of today's preamble are listed in the following outline:

A. Introduction

EPA, in its data collection and information disclosure needs, administers a variety of statutes pertaining to the protection of the environment (e.g., the Toxic Substances Control Act, Resource Conservation and Recovery Act, Comprehensive Environmental Response, Compensation, and Liability Act, Clean Air Act, and Federal Water Pollution Control Act), each with differing data collection requirements and differing requirements for disclosure of information to the public. The Agency collects chemical, process, waste stream, financial, and other data from tens of thousands of facilities in many sectors of American business. Companies frequently consider this information vital to their competitive

position, and claim it as confidential business information (CBI).

In the course of its daily business, the Agency often has a need to communicate CBI during the process of rulemaking, to its contractors, in response to requests under the Freedom of Information Act (FOIA), in litigation, etc. In particular, EPA receives a large number of FOIA requests for an agency its size (exceeded only by three other Federal agencies). The Agency receives upwards of 40,000 FOIA requests annually, and the number of requests grows each year. A large number of these requests encompass information claimed as CBI (although obtaining CBI may not necessarily be the objective of the requestor; see section D., below).

To manage this volume of confidential information while protecting both the confidentiality of competitively valuable information and the rights of FOIA requestors, EPA instituted in 40 CFR part 2, subpart B, a set of procedures for handling and disclosing information claimed as CBI. Although these regulations have succeeded in protecting business information, changes in case law and in Agency workload, practice, and statutory authority require changes in the existing part 2 regulations in order that they may continue to effectively and efficiently guide the Agency in its stewardship of business information. EPA proposes to modify these regulations to eliminate unnecessary procedures, and to streamline and expedite activities involving confidential business information. These proposals are detailed below.

B. Up-front Assertion of and Definition of Confidentiality Claims

EPA proposes to modify § 2.203 so that the Agency would protect only information explicitly claimed as confidential.

1. Assertion of Claims

Before releasing business information to the public, either in response to a FOIA request or otherwise, 40 CFR 2.204 requires that the Agency determine whether the submitter of the information has claimed the information as confidential. If the Agency's records reveal a CBI claim for the information, part 2 provides a series of procedures governing whether and how such information may be disclosed.

Moreover, under existing regulations, even if the submitter has not previously asserted a CBI claim, EPA must inquire whether the submitter wishes to assert a claim if the information is such that the submitter might be expected to object to its release (unless, pursuant to § 2.203(a), the submitter was furnished notice when EPA requested the information that if no CBI claim was asserted when the information was received, EPA may make the information available to the public without further notice). Current regulations thus frequently put Agency employees in the position of having to guess whether a submitter would object to disclosure of the information.

EPA believes that the submitter is in the best position to know whether there would be an objection to disclosure, and that it is unreasonable to expect Agency employees to, in effect, read the mind of the submitter. Therefore, the Agency is proposing to modify § 2.203 so that CBI claims are made upon submission of the information. If review of the Agency's records revealed no claim, the Agency would have no duty to inquire whether the submitter wished to assert a claim. However, if it were obvious that a document not associated with a CBI claim did in fact contain commercially valuable information, the Agency would look into the matter.

This change would not preclude a submitter from filing a CBI claim subsequent to submission of the information, although to the extent that EPA has already disclosed the information or widely disseminated it in the interim may mean that such a claim would in practical effect be too late. This is in fact the Agency's present policy with respect to late claims, as provided in 40 CFR 2.203(c).

One class of submitters which would need to pay close attention to this change is third-party submitters (e.g., Company A, which provides CBI to Company B, which then submits it to EPA). Currently, when the Agency has possession of information developed by Company A and submitted to EPA by Company B, the Agency must determine whether both Company A and Company B are affected businesses that might wish to assert confidentiality claims. Under this change, if the information was submitted by Company B without any indication that it was claimed as CBI, EPA would assume that the information was nonconfidential. Thus, submitters in the position of Company A would as a matter of course need to ensure that, when they provide CBI to someone who may in turn provide the information to EPA, the confidentiality claim is asserted when the information is submitted to EPA. The Agency believes that this is consistent with prudent business practice.

Section 2.203(c) currently provides that, with respect to information submitted before October 1, 1976, EPA must verify with the submitter that no claim is asserted before releasing business information, without regard to whether the submitter knew that information not claimed as confidential may be disclosed to the public. (For information submitted after that date, the Agency need not make such an inquiry if the submitter has received notice that information not claimed as confidential may be disclosed without further notice.) The purpose for this distinction was to protect companies who had submitted information before EPA's regulatory policies for protecting CBI were originally established.

EPA proposes to eliminate the distinction for information submitted before October 1, 1976. The practical effect of this change would be that persons who submitted information prior to October 1, 1976 *and who were given written notice at the time that information not claimed as confidential may be disclosed to the public* would no longer be asked at a later date whether they wished to assert a CBI claim. If, with respect to such information, the Agency had no record that such notice had been given, EPA would continue to inquire, where appropriate, whether the person wished to assert a CBI claim for the information. The Agency believes that when data 17 years old or older were not originally claimed as confidential, and the submitter was given notice that a confidentiality claim must be asserted in order to protect the information, further inquiry is not required.

2. Definition of Claims

Even where a submitter has asserted a confidentiality claim, the claim is frequently asserted merely by claiming an entire submission as confidential, even though very few documents are composed entirely of confidential business information. Where such a blanket claim has been made, the Agency has no way of knowing what specific information in the submission is claimed as confidential. Consequently, Agency employees may be faced with great difficulty in redacting (sanitizing) the documents, or must ask the submitter in each case which information in the submission is subject to a CBI claim. When EPA is dealing with masses of data from hundreds or thousands of submitters, uncertainty as to what specific confidentiality claims are being asserted can be a significant barrier to Agency action. It is therefore important that all CBI claims be asserted with specificity. Nonetheless, the Agency recognizes that there are rare situations in which an entire document may be entitled to confidentiality.

EPA is therefore proposing to modify § 2.203(b) to provide that any confidentiality claim for an entire document be deemed ineffective (i.e., EPA would treat the document as if it were not claimed as CBI) unless at the time of assertion the submitter substantiates why the entire document (as opposed to portions of the document) should be maintained as confidential.

3. Retroactivity

The proposed provisions governing up-front assertion of claims and substantiation of blanket claims for an entire document would apply only to data submitted on or after the date of the final rule.

C. Sanitization and Aggregation of Data

The Agency proposes to modify § 2.202(f) to clarify that a submitter's consent is not required for disclosure of sanitized or aggregated data.

EPA frequently needs to disclose to the public (e.g., pursuant to a FOIA request or in discussions of the bases for Agency decisions) non-confidential information derived from data supplied by businesses and claimed as confidential. Such releases might take the form of industry-wide data aggregated into a non-confidential figure, or sanitized documents where all information that could identify the submitters has been removed.

Sanitization and aggregation of submissions require care to ensure that the information released to the public cannot be used by a knowledgeable person to back-calculate to information claimed as CBI. EPA employees releasing such information frequently have questions concerning the steps to be taken to ensure that CBI is not disclosed. Existing Agency regulations at 40 CFR 2.202(f) provide an uncertain guide, merely stating that EPA "should consider whether it is possible to obtain the affected business's consent" to this kind of disclosure. However, releasing properly sanitized or aggregated data does not disclose information claimed as confidential, and the consent of the submitter to such release is not necessary.

The Agency has long disclosed aggregated data submitted pursuant to the Toxic Substances Control Act (TSCA), without the consent of the submitter, in accordance with published protocols. *See e.g.*, 48 FR 6539 (February 14, 1983). Such disclosures have successfully protected confidential data.

EPA desires to clarify its policy with respect to sanitized and aggregated data. The Agency believes it should provide the public with useful information while ensuring that data claimed as confidential is given sufficient protection. Therefore, the proposed rule contains language modifying § 2.202(f) to clarify that the submitter's consent is not required for disclosure of aggregated or sanitized information, but that: (1) When disclosing sanitized copies, EPA offices must ensure that the portions of the documents which are disclosed do not contain information claimed as confidential; and (2) all disclosures of aggregated numerical data must be made using a procedure on which an EPA legal office (Office of General Counsel or Office of Regional Counsel) has been consulted. In consultation with an EPA legal office, a program would develop and subsequently follow a set of principles involving confidentiality safeguards and allowing scientific or technical adaptability to specific aggregation needs.

D. Requirement to Make a Final Determination of Confidentiality When Information Claimed as Confidential is Requested Pursuant to the Freedom of Information Act

EPA proposes to modify its public information and confidentiality regulations to require final confidentiality determinations only where the requestor has expressly requested information claimed as confidential.

When EPA receives a request pursuant to FOIA which encompasses information claimed as confidential, existing regulations at 40 CFR 2.204(d)(1) require that the request be initially denied with respect to information subject to a confidentiality claim (unless the information is clearly not entitled to confidentiality), pending a final determination by an Agency legal office of the eligibility of the information for confidential treatment under exemption 4 of FOIA. This determination must be made irrespective of whether the requestor appeals the initial denial. Such treatment of exemption 4 denials is in contrast to legal determinations made with respect to denials of records pursuant to other exemptions of FOIA, which under 40 CFR 2.115 (contained in subpart A of part 2, governing requests for information) are made only upon appeal of the denial. The Agency originally devised this process as a means of meeting its obligations under FOIA to make a determination of releasability and adhere to the response times in FOIA of ten days to the extent possible: for most CBI claims, detailed information from the submitter is necessary to make a determination of confidentiality, and making such a final determination requires far more than ten days.

However, making a final determination of confidentiality can be time-consuming and resource intensive for EPA, and requires the submitter to prepare a justification of why the information is entitled to confidentiality. The Agency's experience in responding to such FOIA requests is that requestors are frequently not interested in information claimed as confidential, and the exercise of determining confidentiality in such cases is unnecessary.

EPA is therefore proposing to modify its subpart A provisions so as to require final determinations of confidentiality only where the requestor has expressly indicated a desire for information claimed as confidential. Under the proposed change, § 2.111 (subpart A) and § 2.204(a)(1) (subpart B) would be modified to create a presumption, rebuttable by the FOIA request itself, that the requestor does not desire access to information claimed as CBI. In other words, if a FOIA request which would otherwise encompass information claimed as business confidential is silent as to whether information claimed as CBI is desired by the requestor, EPA would presume that the requestor does not desire such information. If, however, the request states that access to information claimed as CBI is desired, the Agency would treat such requests as it has in the past, i.e., making an initial denial with a subsequent determination as to whether the subject information is entitled to confidential treatment.

EPA realizes that some requestors might not be aware of the necessity to specify that they desire access to information claimed as confidential, or might not know, without first learning what records are in EPA's possession, whether they do in fact require access to information claimed as CBI. Thus, if the Agency merely ignored the portion of the request pertaining to information claimed as CBI, some requestors might never learn that there is pertinent information in the Agency's files which is claimed as confidential. Therefore, § 2.111 would provide that the response to such a FOIA request must state that the Agency is presuming that the request does not encompass information claimed as CBI, and must include in the response a list or description of that information claimed as CBI which EPA was presuming not to be subject to the FOIA request. The requestor could then choose to submit another FOIA request for that information.

Authority to create such a presumption can be found in FOIA itself. Although it is commonly believed that FOIA requires Federal agencies to respond to every request under FOIA which reasonably describes the records sought, FOIA requires that such requests be made "in accordance with published rules stating the * * * procedures to be followed." 5 U.S.C. 552(a)(3)(B). The rebuttable presumption that CBI is not requested would be a procedure under 5 U.S.C. 552(a)(3)(B) which is intended to save both EPA and CBI submitters time and resources, as well as to improve responsiveness to FOIA requests by eliminating unnecessary determinations of confidentiality.

EPA considered a second alternative which adheres more closely to current Agency procedures. Under this alternative, EPA would not make any presumptions as to the scope of the request, and would continue to issue denials with respect to information claimed as CBI, solely on the basis of the confidentiality claim. However, the Agency would not request substantiation or issue a final confidentiality determination unless the requestor appealed the denial. The Agency considers this alternative less desirable because even for those requestors who specifically state a desire for CBI in their request, the lengthy process of substantiation and determination would not begin until the request was appealed. Additionally, this alternative raises a question as to whether EPA would be meeting its obligations under paragraph (a)(3) of FOIA to make non-exempt records available to requestors if it denied requested records merely on the basis of a claim of confidentiality without determining whether in fact such records qualify for withholding under exemption 4 of FOIA.

A third alternative consists of implementing the presumption discussed above *and*, with respect to those FOIA requests which specifically request CBI, only making a final confidentiality determination if the request is appealed (under the theory that requestors who initially indicate a desire for CBI may decide not to appeal once they see a list of what information is actually claimed). This alternative would be the least burdensome for the Agency, but suffers from the same difficulties as the previous alternative; it also would only be worthwhile if a significant proportion of those requestors specifically asking for CBI would in fact not appeal the initial denial.

A fourth alternative is making no change to the present procedures. EPA requests comments on all alternatives.

E. Up-front Substantiation of Confidentiality Claims Upon Submission of Information to EPA

EPA proposes to amend § 2.203(b) to provide a framework for more specific regulatory requirements that CBI claims for specified types of information must be accompanied by a substantiation at the time of submission.

Pursuant to § 2.204, when the Agency either; (1) Is required by a FOIA request, or (2) desires for any purpose, to determine whether information in its possession is entitled to confidentiality, EPA requires the submitter to substantiate its confidentiality claim. The submitter must submit information which, among other things, sets forth:

(1) What portion of the information the submitter believes is entitled to confidential treatment;

(2) The length of time for which confidential treatment is desired;

(3) Measures taken by the business to prevent undesired disclosure to others;

(4) The extent to which the information has already been disclosed to others; and

(5) Why release of the information would result in substantial harmful effects to the business' competitive position in the marketplace. 40 CFR 2.204(e)(4).

EPA's general confidentiality regulations at 40 CFR part 2 do not require a CBI claim to be substantiated upon submission of the information, although some program-specific regulations contain an up-front substantiation requirement. *See, e.g.*, 40 CFR 710.38 and 720.90(b)(2), implementing the Toxic Substances Control Act.

Submission of substantiation material at a later date can be somewhat problematic, both for the submitter and the Agency. It may be more difficult for the submitter to compile responsive information when requested to do so by the Agency long after the information claimed as confidential has been submitted to EPA. Not having this information on hand can impair the Agency's ability to perform some of its functions (especially responding to FOIA requests which seek information that contains CBI) in an expeditious manner.

The Agency is proposing to amend § 2.203(b) to explicitly provide that up-front substantiation requirements may be promulgated on a program-by-program basis by specific regulation. Existing up-front substantiation requirements would not be affected by this change. The need for such a requirement varies among programs and data collections, dependent in part upon the public interest in the information, the frequency of CBI claims, and the frequency of insupportable claims. For example, in programs where CBI claims are infrequent, the impact of confidentiality claims on both the Agency and FOIA requestors is low. Therefore, the proposed amendment would not be self-executing: up-front substantiation requirements would be imposed for specified classes of information by notice and comment rulemaking. This approach would give the Agency the flexibility to impose such a requirement only where necessary.

The Agency believes that such a provision would be beneficial for two principal reasons. First, it would enable EPA to deal in a more expeditious fashion with FOIA requests which seek information containing CBI. In general, such requests can take a long time to resolve, in part due to the process of requesting (and receiving) a substantiation from the submitter. Having the substantiation on file would expedite the process.

Second, the Agency believes that an up-front substantiation requirement would help reduce those CBI claims made as a matter of course and induce submitters to be more selective in their CBI claims by requesting CBI protection only for specific information that truly needs to be protected. The Agency is not seeking to limit the type of information which a party may claim as CBI. Rather, EPA believes that the introduction of a requirement to justify a CBI claim upon submission of the underlying material would induce submitters to request CBI treatment only for information which is truly confidential, thereby reducing the amount of confidentiality claims actually submitted to the Agency. EPA anticipates that this will expedite review of data provided to the Agency, allowing EPA to make determinations concerning CBI claims and respond to FOIA requests more expeditiously. Finally, the Agency does not believe that this amendment would chill a submitter's assertion of a claim for information which is truly entitled to confidential treatment. If information is important enough to be worth confidential protection, it is worth substantiating the claim. The proposed amendment does not codify uniform substantiation questions, but requires all up-front substantiations to address at the least the factors in 40 CFR 2.208 (criteria for confidentiality).

Authority for an up-front substantiation requirement stems both

from the statutes administered by EPA (e.g., section 308 of the Clean Water Act provides that all information collected under this section "shall be available to the public, except that upon a showing satisfactory to the Administrator" the information is entitled to confidential protection), and the Agency's inherent authority to promulgate regulations governing disclosure under the Freedom of Information Act, the Trade Secrets Act, and other statutes (cf. discussion of sunset provisions in section F., below).

F. Expiration of Confidentiality Claims: Sunset Provisions

EPA proposes to add a new § 2.216, which would allow selected CBI claims to expire unless reasserted.

1. Rationale

The commercial utility of information will usually decrease over time: new processes are developed, and market forces change. As the proprietary value of information lessens, at a certain point in time the information may no longer be entitled to confidentiality. It is then appropriate to end confidential treatment. EPA is proposing to allow the promulgation of sunset provisions to identify such points in time.

EPA has long taken the position that "[p]ublic participation cannot be effective unless meaningful information is made available to the interested persons." 48 FR 21737 (May 13, 1983). Information submitted to the Agency under a claim of confidentiality interferes with EPA's ability to inform the public. EPA recognizes its duty to safeguard confidential business information, but believes there are confidentiality claims that are no longer valid. Where there is no longer a reason for a confidentiality claim, the subject information should be declassified to maximize the amount of information publicly available to facilitate public participation in the regulatory process.

2. Operation of Sunset Provisions

EPA proposes to add a new section, § 2.216, to establish a framework within which the Agency may promulgate regulations requiring that a previously asserted confidentiality claim be reasserted during a specified period. The period could follow either submission of the information or the occurrence of a specified event. Examples of hypothetical periods are five years after submission of the information, or within 90 days of granting of a United States patent protecting the information. Because this framework would be implemented by program-specific regulations, § 2.216 would not in itself cause any confidentiality claims to expire. Rather, the provision is intended to establish the necessary components of a regulation which provides for expiration of confidentiality claims.

All submitters asserting confidentiality claims subject to a sunset provision would be given an opportunity to reassert the claim. In addition, the provision would only be applied prospectively.

A regulation with a sunset provision would establish the various parameters of the provision. These include the class of information to which the sunset applies, the period of time or event to occur before the confidentiality claim expires, and the procedures to follow to reassert the claim. A claim which is not reasserted in accordance with the stated procedures would be deemed waived. A specific sunset provision might include, along with a requirement to reassert the claim, a requirement to substantiate (or resubstantiate) the claim at the time of reassertion.

Submitters would be expected to know what information is subject to a sunset provision and the time when reassertion is due. Since the existence of the sunset provision in Agency regulations would itself provide submitters with notice of the reassertion requirement, the Agency would not be required to provide further notice of either the sunset provision or the opportunity to reassert the claim. However, program offices would not be precluded from establishing a policy of routinely providing such further notice.

Where the same information was submitted several times to the Agency, each submission which is subject to a sunset provision would carry its own sunset period. An expired confidentiality claim on one submission would not automatically eliminate the confidentiality claim for a second submission, because the link between the information and the second submission might itself be protectible information, notwithstanding the fact that the information in the first submission is now public. Nonetheless, such situations are unlikely, and the expiration of the claim for the first submission, causing that information to enter the public domain, would play a significant role in determining whether the second submission was now also in the public domain.

3. Authority

EPA believes that the authority to promulgate requirements for maintaining confidentiality claims is inherent in the environmental statutes administered by the Agency which provide that information may be protected upon a showing made to the Administrator that the information is entitled to confidentiality (see, e.g., section 308 of the Clean Water Act). EPA administers numerous statutes which require information to be submitted to the Agency. These statutes contain provisions which either specify the procedures for claiming confidential status or generally describe confidential treatment for information, in concert with general rulemaking authority to implement the statute. These statutory authorities form the basis for the current EPA confidentiality regulations.

For example, the Toxic Substances Control Act (TSCA) states that "[a] designation (of confidentiality) under this chapter shall be made in writing and in such manner as the Administrator may prescribe". 15 U.S.C. 2613(c)(1)(B). EPA has previously construed this provision to authorize a sunset provision which causes certain confidentiality claims associated with Premanufacture Notifications to expire upon submission of a Notice of Commencement, unless the claim is reasserted at that time. *See* 40 CFR 720.85.

Implicit in the prohibition on disclosing confidential information without authority to do so (contained in many of the statutes administered by the Agency and the Trade Secrets Act, 18 U.S.C. 1905) is the authority to provide for assertion of claims and to take those steps necessary to determine which information claimed as CBI is actually entitled to confidentiality. Because information may lose its eligibility for confidential treatment over time, it is a legitimate exercise of statutory authority to reexamine confidentiality claims in a systematic manner via regulations which allow confidentiality claims to expire.

In addition, EPA seeks to more fully embrace the policy stated in Executive Order 12600 § 3(b), 3 CFR, 1987 Comp., p. 236, which explicitly contemplates that Federal agencies may provide for the expiration of confidentiality claims on information submitted to the Federal Government on or after January 1, 1988. The order provides that "agency procedures may provide for the expiration, after a specified period of time or change in circumstances, of designations of competitive harm made by submitters."

4. Other Issues

EPA has considered a number of different issues before arriving at this proposal. First, EPA has considered how broadly a sunset provision should apply. Specifically, the Agency considered whether regulations should

provide for a uniform sunset requirement for all submissions, Agency-wide, or for a program-by-program sunset requirement based on the individual program's needs. The Agency has concluded that, at a minimum, the need for a sunset provision and the determination of the appropriate sunset period depend upon, among other things, the nature of the information, the public interest in the information, and the frequency of confidentiality claims, all of which vary according to the type of information involved. Therefore, the Agency has decided that it is more appropriate that sunset provisions be put into place on a program-by-program basis. The purpose of proposed § 2.216 is to establish a regulatory framework for how sunset provisions would operate.

EPA has also considered whether the Agency should be required to remind submitters when their claims are about to expire. EPA is proposing not to provide such a reminder, but is placing on submitters the responsibility for ensuring that they reassert the confidentiality claim at the appropriate time. EPA believes that putting the burden on the Agency to notify the submitter before expiration of the claim would be little different than what is provided under existing regulations, because EPA can already in effect give a submitter notice that a claim will expire unless the submitter responds to the notice. Under current § 2.204(e) EPA can require a submitter to substantiate a claim; if the submitter does not respond in a timely manner, under § 2.205(d) the claim is deemed waived. Although making submitters responsible for determining when action must be taken would require them to maintain the necessary information to make such a determination, it is a matter of sound business practice to keep track of what information has been submitted to EPA and what actions are required to safeguard the information (and when to take such actions). Those claims which are worth asserting for a significant period of time are also worth the associated recordkeeping.

Finally, EPA has considered whether submitters should be required to substantiate a reasserted claim at the time of the reassertion. EPA believes that the answer to this question depends upon factors such as the nature of the data, the likelihood that old data would continue to need confidential treatment, and the uses made by the Agency and the public of such data. Therefore, EPA proposes to leave that issue to be decided on a case-by-case basis during promulgation of specific sunset provisions. However, such a requirement could be placed in an individual regulation, where appropriate.

G. Eligibility of Voluntarily-submitted Information for Confidential Treatment

EPA proposes to amend several sections in part 2 to make the regulations consistent with the recent decision in *Critical Mass v. Nuclear Regulatory Commission*, 975 F.2d 871 (D.C. Cir. 1992), *cert. denied*, 113 S. Ct. 1579 (1993).

1. Critical Mass

At the time of the Agency's original promulgation of its confidentiality regulations at 40 CFR part 2, subpart B, the applicable standard for whether information was entitled to confidential treatment under Exemption 4 of the Freedom of Information Act was set forth in *National Parks and Conservation Association v. Morton*, 498 F.2d 765 (D.C. Cir. 1974). In *National Parks*, the Court set forth a two-part test, stating that "[c]ommercial or financial matter is 'confidential' * * * if disclosure of the information is likely * * * either * * * (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained." 498 F.2d at 770.

In *Critical Mass*, the D.C. Circuit revisited the definition of "confidential" set forth in the *National Parks* case. The Court did not abandon the definition of "confidential" presented in *National Parks*, but chose to modify its application. The categorical rule developed by the Court states that "financial or commercial information provided to the Government on a voluntary basis is confidential for the purpose of Exemption 4 if it is of a kind that would customarily not be released to the public by the person from whom it was obtained." 975 F.2d at 879. Therefore, if commercial or financial information obtained from a person is submitted voluntarily and would not customarily be disclosed by the submitter, it is presumed confidential without requiring any examination of the competitive harm portion of the *National Parks* test. EPA proposes to amend the criteria for confidentiality in § 2.208 accordingly.

Note that information which under *Critical Mass* is entitled to confidentiality pursuant to exemption 4 of FOIA may still be required to be disclosed to the public via independent statutory authority. For example, emission data which could have been collected pursuant to section 114 of the Clean Air Act but was in fact voluntarily submitted to EPA would not be eligible for confidential treatment, due to the requirement in section 114 that emission data be available to the public.

2. Definition of "Voluntarily Submitted"

Section 2.201(i) currently provides that for information to be considered voluntarily submitted it must be information whose submission EPA had no statutory or contractual authority to require. However, in *Critical Mass*, information which the court called voluntarily submitted was within the statutory authority of the Nuclear Regulatory Commission to require from the regulated industry, although the Commission had not in fact required its submission; rather, the Commission had obtained the information on a voluntary basis from an industry association. 975 F.2d at 880. Because the § 2.201(i) definition appears to conflict with *Critical Mass*, and the courts have only begun to determine when information is submitted voluntarily, EPA proposes to delete § 2.201(i) altogether.

3. Requests for Substantiation

Because the confidentiality of voluntarily submitted information is not dependent on competitive harm, there is no need for the Agency to require submitters to justify why disclosure of such information is likely to cause substantial competitive harm. Therefore, EPA proposes to modify the substantiation requirements at § 2.204(e)(4) to allow the action office to not request substantiation on competitive harm when the action office believes the information was submitted voluntarily. The Agency would ask questions eliciting information which pertains to whether such information would customarily be disclosed to the public by the submitter. If the EPA legal office which subsequently determines the information's eligibility for confidential treatment believes that the information is in fact not voluntarily submitted, the legal office would request the submitter to substantiate the likelihood of competitive harm, pursuant to the procedures of § 2.204(e).

4. Advance Confidentiality Determinations

Under § 2.206, EPA may make an advance determination of confidentiality before information is officially submitted to the Agency, provided that: (1) EPA has requested or demanded that a business furnish business information to the Agency, (2) the submitter asserts that the information would constitute voluntarily submitted information, and

(3) the submitter will voluntarily submit the information for use by EPA only if EPA first determines that the information is entitled to confidential treatment. Section 2.206 currently cites the definition of voluntarily submitted in § 2.201(i), and requires substantiation of competitive harm. EPA proposes to delete both the reference to § 2.201(i) and the requirement to substantiate competitive harm.

EPA also proposes to remove the words "or demanded" from § 2.206(a)(1). This change would clarify that where EPA demands submission of information pursuant to its authority, the information cannot be deemed voluntarily submitted.

5. Class Determinations

Under § 2.207, EPA may make determinations pertaining to, among other things, whether information is submitted voluntarily (for a more detailed discussion of class determinations, see section K., below). Section 2.207 currently refers to the § 2.201(i) definition of voluntarily submitted information; this reference would be deleted.

H. Implementation of Final Determinations by Program Offices

EPA proposes to amend § 2.205(f) to permit program offices to grant extensions of time and release information pursuant to final confidentiality determinations made by those offices under § 2.204(d)(2).

Final determinations of confidentiality are normally made by a legal office (General Counsel or Regional Counsel) under § 2.205. However, when information is clearly not entitled to confidentiality, under § 2.204(d)(2) any office may make a final confidentiality determination. Section 2.205(f) provides procedures to follow any determination that information is not entitled to confidentiality (either under § 2.205 or § 2.204(d)(2)): advance notification to the submitter of disclosure of the information within a certain period (normally ten days), extension of the time period in certain cases, and disclosure of the information if the submitter does not file suit during this period to enjoin disclosure.

Section 2.205(f) does not clearly state that a program office may grant extensions of the time period and ultimately disclose the information upon its expiration when the final determination was drafted by the program office, although such a practice would be logical and efficient. EPA proposes to amend § 2.205(f) accordingly.

I. Delegation of Authority to Perform Functions Under Part 2

EPA proposes to amend several sections to give the General Counsel greater flexibility in delegating part 2 functions.

40 CFR 2.205(i), as supplemented by § 2.306(e)(1) (governing TSCA confidentiality), § 2.307(e)(1) (governing confidentiality under the Federal Insecticide, Fungicide, and Rodenticide Act), and § 2.308(f)(1) (governing confidentiality under the Federal Food, Drug and Cosmetic Act), sets limits on who can take certain actions under part 2, such as issuing final determinations of confidentiality under § 2.205. Following are proposals to amend these limitations to give EPA more flexibility in its internal operations.

1. Final Confidentiality Determinations With Respect to Data Submitted Under the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Federal Food, Drug and Cosmetic Act (FFDCA)

Section 2.205(i) provides that final confidentiality determinations may be made by EPA legal offices (Office of General Counsel or Offices of Regional Counsel). However, §§ 2.306(e)(1), 2.307(e)(1), and 2.308(f)(1) provide that "the General Counsel (or his designee), rather than the Regional Counsel," may make confidentiality determinations for data submitted pursuant to TSCA, FIFRA, or FFDCA, respectively. The Office of General Counsel has consistently interpreted these provisions to allow the General Counsel to designate the Regional Counsels to make TSCA, FIFRA and FFDCA confidentiality determinations. EPA proposes to amend these provisions to provide that Regional Counsels may make final determinations under TSCA, FIFRA, and FFDCA. (Note: under revisions discussed below, § 2.306(e) would be redesignated as § 2.306(f).)

2. Delegation of Part 2, Subpart B Functions to Part-time Attorneys

Section 2.205(i) provides that the General Counsel "may redelegate any or all of his authority under this subpart to any attorney employed by EPA on a full-time basis under the General Counsel's supervision." The section contains similar language regarding Regional Counsels. The limitation to full-time attorneys was originally promulgated to be an internal management tool for the Agency. However, the Agency now believes that the decision as to the ability of part-time attorneys to fill a function is best left to the judgment of the delegating official rather than being constrained by regulation, and proposes to remove this limitation.

J. Definition of Legal Office

EPA proposes to amend § 2.201(n) to reflect the reorganization of 1990 involving the reporting relationships of Regional Counsels to the Office of Enforcement and Compliance Assurance and the Office of General Counsel.

Under part 2 regulations, some actions may be taken by any office (e.g., initially denying a FOIA request encompassing CBI), while some actions may only be taken by a "legal office" (e.g., final confidentiality determinations pursuant to § 2.205(a)). Section § 2.201(n) defines an EPA legal office as "the EPA General Counsel, and any EPA office over which the General Counsel exercises supervisory authority, including the various Offices of Regional Counsel."

Since 1990, the Offices of Regional Counsel (ORC) have reported to EPA's Office of Enforcement (now the Office of Enforcement and Compliance Assurance), rather than the Office of General Counsel, although ORC maintains the same functions with respect to EPA's confidentiality regulations. Therefore, EPA proposes to amend § 2.201(n) to reflect this organizational change.

K. Class Determinations

EPA proposes to modify § 2.207 to require publication in the **Federal Register** of future class determinations.

Under § 2.207, EPA may issue a class determination finding that there is a class of information such that one or more characteristics common to all items in the class will necessarily result in identical treatment for each such item under one or more of the provisions in EPA's confidentiality regulations. EPA has issued seventeen class determinations.

Most commonly, a class determination states whether the class is entitled to confidentiality. When the Agency is contemplating disclosure of information subject to a class determination, the notice of opportunity to submit comments referred to in §§ 2.204(d)(1)(ii) and 2.205(b) may be modified to reflect the fact that the class determination has made unnecessary the submission of materials pertinent to one or more issues.

EPA has generally published such class determinations in the **Federal Register**, and § 2.207(d) provides that "[t]he purpose of a class determination is simply to make known the Agency's position regarding the manner in which information within the class will be

treated." Nonetheless, § 2.207 currently does not require publication. Although class determinations are not rules subject to the notice and comment requirements of the Administrative Procedures Act, EPA believes that publication of all future class determinations in the **Federal Register** would be consistent with the purpose of making known the Agency's position on the class, and is in the best interests of submitters of confidential information, FOIA requestors, and the Agency itself. Publication would also be consistent with the requirement in the Freedom of Information Act, 5 U.S.C. 552(a)(1)(D), that agencies publish in the **Federal Register** "interpretations of general applicability formulated and adopted by the agency." Therefore, EPA is proposing to modify § 2.207 to provide for publication in the **Federal Register** of future class determinations.

L. Effect of Previous Confidentiality Determinations

EPA proposes to modify § 2.204(b) to clarify (or in some situations increase) the ability of the Agency to rely on previous confidentiality determinations by EPA, Federal courts, and State and local governments.

When EPA is determining whether information is entitled to confidentiality, § 2.204(b) requires the Agency to ascertain whether there has been a previous confidentiality determination by a Federal court or EPA legal office. The normal method of learning about previous determinations is to ask the submitter, who would have the most comprehensive file of relevant determinations. If the information has previously been determined by a Federal court or EPA legal office to be entitled to confidentiality, the Agency does not reexamine the issue. Instead, the Agency denies any pending FOIA requests for the information, and considers the matter closed, unless the previous determination was issued by EPA and the Agency now believes that the previous determination was erroneous. Pursuant to § 2.205(h), a legal office may modify a previous determination believed to be erroneous.

The purpose of § 2.204(b) is to save the time and resources otherwise required to decide the issue anew. However, § 2.204(b) fails to provide for any effect of either (1) A previous determination by a Federal court or EPA legal office that the information is *not* entitled to confidentiality, or (2) a determination by a State or local governmental body. Additional savings could be realized if such determinations had similar effect.

1. Previous Determinations by a Federal Court or EPA Legal Office That Information Is Not Entitled to Confidentiality

Arguably, such situations are already covered by existing regulations. Section 2.204(d)(2) allows an EPA office to issue a determination that information is clearly not entitled to confidentiality, without giving the submitter an opportunity to substantiate the claim. In the **Federal Register** of September 1, 1976 (41 FR 36920, discussion of comment #16) the Agency stated that such a determination can be made where "EPA's position on the matter is already clear and there is nothing further to consider." A previous confidentiality determination clearly falls within that category. Furthermore, on page 36919, in response to comment #13, the Agency stated that "[e]ven if a prior determination states that information of a certain type is not entitled to confidential treatment, a business should be afforded the opportunity to seek judicial review." The Agency did not in that sentence discuss an additional opportunity for the submitter to substantiate the CBI claim, indicating that a § 2.204(d)(2) determination was contemplated by EPA as the appropriate procedure when the Agency has previously determined that the information was not entitled to confidentiality.

Nonetheless, in the interest of clarity, EPA now proposes to amend § 2.204(b) to make it explicit that a previous determination by an EPA legal office or a Federal court denying confidentiality is grounds for a § 2.204(d)(2) determination.

2. Previous Determinations by a Federal Agency or by a State or Local Government Entity

Confidentiality determinations by other Federal agencies or by State and local governments are not binding upon EPA, and in the case of State or local determinations may be based upon inapplicable State or local laws. Thus, the legal opinion of another Federal agency or of a State or local government as to whether information is entitled to confidentiality could only be useful to EPA in an advisory capacity. However, where the government entity has determined that the information is not entitled to confidentiality and has released the information to the public based upon that determination, the information has now entered the public domain, and is no longer entitled to confidentiality, regardless of whether EPA agrees with the rationale for the original determination by the governmental entity. Therefore, the Agency proposes to modify § 2.204(b) to provide that, where another Federal agency or a State or local government entity has determined that information is not entitled to confidentiality and the information is available from that entity (e.g., if the submitter has exhausted all administrative remedies with the governmental entity), the information is clearly not entitled to confidentiality under § 2.204(d)(2).

M. Agency Requirements When Requesting Comments Justifying a Confidentiality Claim; Untimely Responses

EPA proposes to amend § 2.205 to expedite procedures for sending out requests for substantiation and to codify Class Determination 1–85, regarding untimely responses to substantiation requests.

When EPA is determining whether information claimed as confidential is entitled to confidentiality, and asks an affected business to substantiate a CBI claim, the business is given a period (usually 15 working days) to submit its substantiation. 40 CFR 2.204(e). Failure to submit the substantiation within this period (or any approved extension of time) results in a finding that the submitter has waived its claim. 40 CFR 2.205(d)(1).

1. Agency Requirements to Verify Receipt and Response

Because of the adverse consequences of such failure, EPA's regulations require the Agency to go to considerable lengths to ensure that the submitter files a response to the substantiation request:

(1) EPA must send the substantiation request to the submitter via certified mail (return receipt requested), by personal delivery, or by other means which allows verification of the fact and date of receipt;

(2) The Agency must orally inform a responsible representative of the business that the business should expect to receive the written notice, and must request that the business contact the EPA office if the written notice has not been received within a few days; and

(3) If the substantiation has not been received within the required period, the Agency must contact the affected business, ask whether the substantiation had been lost in transmission, and provide an opportunity to resubmit the comments. 40 CFR 2.204(e) and 2.205(b).

Although EPA continues to believe it is appropriate to adequately document receipt of the substantiation request and to verify that the substantiation was indeed submitted (given the size of the

Agency and the chances that a submission might be significantly delayed in finding its way to its intended recipient), the advance oral notification is not necessary, since businesses as a matter of course do read and respond to their mail. Therefore, EPA proposes to delete the requirement in § 2.204(e)(3) that submitters be notified orally of the impending substantiation request. Note that EPA would continue to send the request by means which allow verification of receipt.

2. Codification of Class Determination 1–85

Section 2.205(d)(1) provides that if an EPA legal office finds that a submitter has not filed a timely substantiation, the claim is waived. To avoid the necessity of a legal office making such a finding each time a submitter fails to file a timely substantiation, in 1985 EPA issued Class Determination 1–85. This class determination provides that a business has waived its confidentiality claim, and therefore that no confidentiality claim applies to the relevant information, if both of the following conditions are met:

(1) The EPA office designated to receive the business' comments has not received those comments within the specified time period or an approved extension thereof (see 40 CFR 2.205(b)(2)) as defined by EPA's regulations (40 CFR 2.205(b)(1)–(4)) (after making appropriate inquiry on whether the comments were lost in transmission, as required by 40 CFR 2.205(b)(4)); and

(2) The business was notified in writing at the time comments were solicited that failure to submit timely comments would be construed as a waiver of the business' claim. The effect of such a waiver is that (unless some other business has claimed the information as CBI) no confidentiality claim applies, and the information may be made available to the public.

Although the class determination, pursuant to § 2.207, is effective in allowing disclosure of such information without further notice, it would be clearer if 1–85 were codified in § 2.204(d), instead of requiring an additional non-regulatory document. EPA therefore proposes to modify § 2.204(d)(3), and delete § 2.205(d)(1), accordingly.

N. Advance Notice of Disclosure of CBI to Persons Authorized To Receive It; Recordkeeping of Disclosures

EPA proposes to modify §§ 2.301(h), 350.23(b)(3), and 2.209(g) to streamline and clarify procedures for disclosure of CBI where authorized to do so.

Section 2.301(h)(2)(iii) requires that before CBI may be disclosed to an Agency contractor or subcontractor, advance notice must be given to all affected businesses of the nature of the information to be disclosed, the identity of the contractor or subcontractor, the contract or subcontract number, and the purpose of the disclosure. Affected businesses must be given at least 5 days to comment on the proposed disclosure. Similarly, § 2.301(h)(3)(ii) provides for advance notice of disclosures to State and local governmental entities.

In addition, § 2.301(h)(2)(iv) requires EPA offices disclosing CBI to contractors to create a record of each disclosure, showing the contractor or subcontractor, the contract or subcontract number, the information disclosed, the date(s) of disclosure, and each affected business; this record must be kept for at least three years. Similarly, under § 2.209(g), such a record must be kept with respect to disclosures to Congress, a committee or subcommittee of Congress, the Comptroller General, or another Federal agency. The following paragraphs discuss proposed modifications to these requirements.

1. Form of Notice

Although neither § 2.301(h)(2)(iii) nor § 2.301(h)(3)(ii) state the medium of the notice, the Agency's long-standing practice and interpretation is that such notice may be given at least by letter or **Federal Register** notice. EPA proposes to amend these paragraphs to make explicit that notice in the **Federal Register** is one method of meeting the requirements of these provisions.

EPA is also proposing to similarly amend § 350.23(b)(3) (governing EPCRA trade secret information), a provision equivalent to § 2.301(h).

2. Contract or Subcontract Number

Because §§ 2.301(h)(2)(iii) and 350.23(b)(3) require that the notice include the contract number, whenever EPA enters into a new contract with the same contractor to do the same work as under a pre-existing contract, a new **Federal Register** notice must be published (or set of letters sent out), because the contract number has changed. EPA believes the additional notice is a waste of Agency resources without benefit to submitters, who already have notice of what information is being provided to which contractor. Therefore, the Agency proposes to eliminate the requirement to give notice of the contract or subcontract number.

3. Response to Comments

Although a period for comments is provided by § 2.301(h)(2)(iii), the provision does not stipulate EPA's responsibilities when comments are received. The Agency proposes to revise the provision to make explicit the requirement to respond to comments by affected businesses. EPA proposes to similarly revise § 350.23(b)(3) (governing disclosure of EPCRA trade secret data to authorized representatives).

4. Records of Disclosures

Offices administering several environmental statutes (e.g., the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)) have developed security manuals requiring extensive document tracking activities. Those offices have concluded that the sensitivity and volume of the business information they handle require such procedures. However, EPA as a whole has not determined that there is an Agency-wide need to track every piece of paper it receives. The requirements of §§ 2.209(g) and 2.301(h)(2)(iv) are most appropriate for a TSCA or FIFRA security scheme, and are not necessary for the entire Agency, especially given the good track record of the Agency, its contractors, and other Federal agencies in handling CBI. Therefore, EPA proposes to delete §§ 2.209(g) and 2.301(h)(2)(iv); Agency offices would continue to include such a requirement in their internal security procedures, where appropriate.

O. Disclosure to Foreign Governments and International Organizations

EPA proposes to amend § 2.209 to provide for disclosure of CBI to foreign governments and international organizations where authority for such disclosure exists.

EPA may need to disclose confidential information to foreign governments or international intergovernmental bodies, such as the United Nations, e.g., to assist in law enforcement activities or pursuant to statutory requirements (see, e.g., export regulations implementing section 12(b) of the Toxic Substances Control Act at 40 CFR Part 707). 40 CFR 2.209, governing disclosures of CBI in general, does not include a provision for disclosure to foreign governments or international organizations, even though authority for such disclosure might be found in treaties or other agreements entered into by the United States.

EPA therefore proposes to include a provision in § 2.209 allowing such

disclosure where the Office of General Counsel finds that there is authority for such disclosure. Disclosure to foreign governments or international organizations would involve several safeguards:

(1) A written request for disclosure would be required (unless EPA made a written determination that such disclosure was necessary to assist the Agency in carrying out one of its functions or to enable EPA to assist the government or organization with a duly-authorized function of that entity);

(2) The General Counsel would have to determine that the Agency has authority for the disclosure requested;

(3) Disclosure must be pursuant to law and procedures which will provide adequate protection to the interests of affected businesses; and

(4) advance notice of disclosure would be provided to affected businesses.

One exception to advance notice would exist: Notice would not be provided of a disclosure in the course of a criminal or other law enforcement investigation. EPA works in conjunction with other governments and international law enforcement agencies, such as INTERPOL, in an increasing number of transboundary environmental investigations. The confidential exchange of information, without risk of disclosure to possible subjects of the investigation, can be essential in preventing an investigation from being compromised. To ensure that disclosure to an international body without notice to the submitter occurred only when necessary, the rule would require a determination by the Director of the Office of Criminal Enforcement (in the case of criminal investigations) or the Office of Regulatory Enforcement or the appropriate Office of Regional Counsel (in the case of civil investigations) that providing such notice would interfere with a criminal or civil law enforcement investigation before disclosure could be made without notice.

P. Safeguarding of Confidential Information by Enrollees Under the Senior Environmental Employment (SEE) Program

EPA proposes to amend § 2.211 to include SEE enrollees within its coverage.

On February 5, 1993, EPA promulgated a rule (58 FR 7187), authorizing disclosure of confidential data, submitted pursuant to certain environmental statutes administered by the Agency, to persons participating in the Senior Environmental Employment (SEE) Program. This program is authorized by the Environmental Programs Assistance Act of 1984 (Pub. L. 98–313), which provides that the Administrator may "make grants or enter into cooperative agreements" for the purpose of "providing technical assistance to Federal, State, and local environmental agencies for projects of pollution prevention, abatement, and control."

The rule treated grantees/cooperators under the SEE Program in the same fashion as contractors, requiring that protective clauses be inserted into the SEE grants and cooperative agreements.

However, the rule did not correspondingly amend 40 CFR 2.211, which requires Federal employees, contractors, and contractor employees to protect CBI (this requirement is in addition to that imposed by contract and statute). EPA proposes to include SEE grantees and enrollees within the ambit of § 2.211.

Q. Disclosure to Federal Agencies for Law Enforcement Purposes

EPA proposes to amend § 2.209(c) to provide that no notice is required when the Agency discloses CBI to other Federal agencies for law enforcement purposes.

Under 40 CFR 2.209(c), CBI may be disclosed to other Federal agencies with advance notice to the submitter. The only existing exception to the notice requirement is when the other agency is performing a function on behalf of EPA, e.g., representation by the Department of Justice. However, occasions may arise when EPA needs to cooperate with other agencies on a law enforcement investigation, in which the other agency would not be performing a function on behalf of EPA, but would, primarily, be pursuing its own investigation. Examples of such cases include the investigation of procurement fraud on contracts with more than one Federal agency or the violations of environmental laws by companies whose activities are under the jurisdiction of more than one agency. In such cases, prematurely notifying the submitter of the transfer of CBI might jeopardize the investigation or discourage the other agency from cooperating with EPA.

Therefore, EPA is proposing to amend § 2.209(c) to provide that no notice need be given to affected businesses of disclosure of CBI to another Federal agency in the course of a law enforcement investigation.

R. Reconciliation of Program-Specific Confidentiality Provisions With Part 2

EPA proposes to cross-reference part 2 to specific confidentiality provisions currently contained in specific program regulations outside of part 2.

40 CFR part 2, subpart B regulates treatment of confidential data by the Agency, and includes special provisions for each major environmental statute administered by EPA. However, many program-specific regulations outside of part 2 (e.g., Clean Air Act regulations in 40 CFR parts 57, 85 and 86, and Toxic Substances Control Act regulations in parts 710 and 720) contain confidentiality provisions which, in some cases, differ from those of part 2.

EPA has always considered the program specific confidentiality regulations as supplemental to part 2. However, the lack of reference to such regulations in part 2 can be confusing both for the Agency and for persons attempting to understand and comply with EPA's confidentiality regulations. In determining how to resolve such confusion, the Agency had to deal with competing considerations. First, the Agency should be as consistent as possible in its treatment of CBI. On the other hand, each program within the Agency is working with a different statute (with slightly or significantly varying confidentiality provisions) and operates in a different milieu of data, confidentiality claims, and public interest in the information.

EPA is proposing to cross-reference existing program specific confidentiality regulations in part 2 (the original provisions would also remain in their respective parts). In some cases, minor changes would be made to the program specific regulations where tighter conformance with part 2, subpart A general regulations is desirable. These changes are discussed on a statute-specific basis below.

The proposed reconciliation of program-specific CBI provisions with part 2 does not affect 40 CFR part 350, governing trade secrecy under the Emergency Planning and Community Right-to Know Act of 1986.

S. Changes to Rules Governing Certain Information Obtained Under the Clean Air Act

1. Applicability of 40 CFR 2.301, Special Rules for the Clean Air Act

EPA proposes to amend § 2.301(b)(1)(ii) to comport with the language of section 208(a) of the Clean Air Act, as amended in 1990. In particular, the Clean Air Act Amendments expanded EPA's authority under section 208(a) to obtain information "to otherwise carry out the provision of (part A) and part C" of the Clean Air Act. Also, the language makes clear that EPA's authority under section

208(a) relates specifically to part A and part C of Subchapter II of the Clean Air Act.

2. Basic Rules Which Apply Without Change and Assertion of Claims

Section 2.203(c) allows businesses as a general matter to assert late confidentiality claims. Specific Clean Air Act regulations in parts 57 and 85 of Title 40 differ by providing that confidentiality claims must accompany the information at the time it is submitted to EPA. In addition, certain Clean Air Act regulations require that a sanitized version of the information must be provided and that CBI claims must be indicated by bracketing, stamping, or otherwise specifying the claimed information in order to assert that information submitted is confidential. Finally, in 40 CFR 85.408, EPA's motor vehicle regulations additionally require specific labelling and numbering of documents claimed confidential. EPA is proposing changes here to § 2.301 (c) and (d) to incorporate these specific Clean Air Act requirements into part 2.

3. Changes to Specific Clean Air Act Regulations Under Parts 57, 85 and 86

EPA is proposing additional minor changes to Clean Air Act regulations to reconcile those regulations with the changes being proposed for part 2. Specifically, EPA is proposing to amend references to § 2.204(c)(2)(i)(A). That provision currently specifies that in certain cases where a submitter might have been expected to assert a confidentiality claim but did not, the EPA office shall contact the business to inquire whether the business asserts a claim covering the information. Since EPA is proposing that this inquiry provision be deleted (prospectively only, see section B., above), references to the provision in Clean Air Act regulations should apply only to data submitted before the date the change to § 2.204(c)(2)(i)(A) becomes final. Also, the provisions currently contain references to **Federal Register** notices publishing outdated versions of part 2 rules; EPA would delete these references.

4. Substantive Criteria for Confidentiality Determinations: Production and Consumption Allowances Under Title VI

Section 602 of the Clean Air Act provides for additions to the lists of class I and class II ozone depleting substances. Section 607 specifies that the Administrator shall promulgate regulations providing for production and consumption allowances of these substances. As explained in detail below, the Act without exception compels the public disclosure of companies' production and consumption allowances for such newly listed substances; such disclosure is likely to result in the release of information otherwise regarded as confidential. Congress specified that the allowances are to be based on companies' individual production and consumption levels. Therefore, upon promulgation of a final rule listing a new ozone depleting substance as a class I substance, the Agency believes that this information should not be entitled to treatment as CBI. This is consistent with the position the Agency has taken in an information collection request for information regarding production and consumption of methyl bromide. 58 FR 15014 (March 18, 1993).

It is unnecessary to treat information as CBI or to undertake regulatory procedures to disclose CBI where the statute directly requires that specific information be disclosed. As explained below, the Clean Air Act compels the Agency to disclose specific information related to the establishment of limits on ozone-deplefing substances. Therefore, the Agency believes that this information is not eligible for confidential treatment.

The relevant provisions of Titles III and VI of the Clean Air Act require the Agency to disclose company- and chemical-specific production and consumption allowances for a newly listed substance, at least where the company produces or consumes only one such newly listed substance. Sections 604 and 607 together require that EPA issue company- and chemical-specific allowances for production and consumption of newly listed substances. Section 604 imposes production and consumption limits on each company based on the company's baseline year production and consumption of the newly listed substance. A company is limited to a specified percentage of its baseline year production and consumption of the particular chemical. Section 607 requires EPA to "promulgate rules * * * providing for the issuance of allowances" for the production and consumption of listed substances. Under this provision, EPA is to issue specific allowances in accordance with production and consumption limits. Particularly where allowances are issued for a single newly listed substance, disclosure of a company's allowances based on baseline year production and consumption levels would disclose what might ordinarily be considered CBI.

Congress enacted sections 604 and 607 against the regulatory backdrop of EPA's regulations implementing the Montreal Protocol under existing Clean Air Act authority (former section 151(b)). The Agency implemented the Protocol production and consumption limits through rulemaking establishing company-specific allowances. *See* 53 FR 30566 (August 12, 1988) (implementing the Montreal Protocol and allotting production and consumption allowances to producers and importers). The adoption of sections 604 and 607 in the 1990 Amendments indicates that Congress intended to continue the Agency's company-specific approach. Section 604 requires that production and consumption limits apply on a company-specific basis. Section 607 requires that allowances be based on these company-specific limits. The Agency's current regulations under section 607 comport with this approach. *See* 56 FR 9518 (March 6, 1991) (temporary final rule implementing 1991 production and consumption limits under section 604); 56 FR 49548 (Sept. 30, 1991) (Notice of Proposed Rulemaking to implement 1992 and later production and consumption limits under section 604). Title VI calls for issuance of company- and chemical-specific allowances for listed substances.

Further, under section 307(d)(1), of the Clean Air Act, the public participation and disclosure provisions of section 307(d) apply to "promulgation or revision of regulations under Title VI." Therefore, the allowances must be published for public comment to be legally binding and enforceable. In addition, under section 307(d)(3), the Agency is obligated to include the factual basis for the allowances in the docket for the rulemaking and to include a summary of the factual data in the statement of basis and purpose for the proposed and final rule.

The Clean Air Act's citizen suit provision further confirms that Congress intended Title VI production and consumption limits be disclosed to the public. Section 304 authorizes "any person" to commence a civil action alleging a violation of an emission standard or limitation under the Act. Section 304(f) defines "emission standard or limitation under this Act" to include, *inter alia*, "a schedule or timetable of compliance, emission limitation, standard of performance or emission standard," and thus includes title VI production and consumption limits. Public disclosure of company- and chemical-specific production and consumption limits is necessary for

citizens to challenge violations of those limits.

Therefore, EPA proposes to amend § 2.301(e) to provide that production and consumption allowance information is not entitled to confidential treatment.

5. Confidentiality of Certain Emission Data

EPA is proposing a new § 2.301(e)(2) to specifically identify emission data that are not entitled to confidential treatment and, notwithstanding a confidentiality claim, may be disclosed without further notice. This proposal would codify current EPA policy regarding categories of data that may be excluded from the trade secret definition. That policy was published at 56 FR 7042 (February 21, 1991). As EPA explained in that notice, EPA believes that some kinds of data will always constitute emission data within the meaning of section 114(c) of the Act. The list of types of data specified here is not intended to be a comprehensive list of those types of data which are not entitled to confidential treatment, but is intended to facilitate the use of these data without the need for further processing of confidentiality claims. EPA believes that the information identified is sufficiently specific that a case-by-case evaluation of whether data submitted is covered by the new § 2.301(e)(2) is not necessary.

6. Confidentiality of Gasoline Performance Baselines

On December 15, 1993, EPA issued final regulations for the Clean Air Act's reformulated and conventional gasoline programs. This rule was published on February 16, 1994 (59 FR 7716). The regulations require that refiners and importers of gasoline submit certain information to EPA concerning the quality of the gasoline they produced or imported in 1990. From this, EPA establishes an individual baseline for the refinery or importer. In large part, the individual baseline then becomes the refiner's or importer's performance standard for conventional gasoline. In effect, the quality of their gasoline must on average meet or exceed specified standards set at their 1990 individual baseline levels. A similar approach is used in the reformulated gasoline program for certain standards, however, these standards only apply to certain fuel parameters and only apply for the first three years of that program.

The regulations concerning individual baselines include two provisions relating to public disclosure of this information. First, under 40 CFR 80.93(b)(6)(i) EPA will publish the individual standards for each refinery and importer, including baseline emissions. In addition, under 40 CFR 80.93(b)(6)(ii) EPA determined that certain information provided by the refiner or importer in their individual baseline submission would not be considered confidential, under the theory that such information constitutes emission data.

Various interested parties have since sought judicial review of these individual baseline regulations, including those provisions governing confidentiality. In light of this litigation, and to avoid confusion, EPA is not proposing today to cross reference these individual baseline regulations in § 2.301, but instead will determine the appropriate revision to part 2 at a later time. In the meantime, the confidentiality provisions in 40 CFR 80.93(b)(6) remain in effect.

T. Changes to Rules Governing Certain Information Obtained Under the Clean Water Act

The Agency is proposing amendments both to its supplemental CBI regulations at § 2.302 and to certain other regulations in Title 40 which relate to the handling of CBI under the Clean Water Act (CWA). These changes are intended to make CWA confidentiality provisions published in 40 CFR parts 122, 123, 233, 403 and 501 consistent with the provisions, including the changes proposed today, in 40 CFR part 2.

1. Substantive Criteria for Use in Confidentiality Determinations

The Agency is proposing to amend the part 2 supplemental CWA provision (§ 2.302) to incorporate, for purposes of consistency, certain limitations on confidentiality currently provided by the CWA regulatory provisions (§§ 122.7, 233.3, and 501.15). These sections provide that: (1) Effluent data, (2) the name and address of any permit applicant or permittee, and (3) any permit application (including any attachments used to supply information required by the application forms) or permit are not eligible for confidential treatment. This change to § 2.302 would not substantively alter the Agency's approach to CBI under the CWA.

2. Changes to Specific Clean Water Act Regulations

Under Parts 122, 123, 233 and 403

As discussed in section B., above, the Agency is proposing to amend § 2.203 to provide that any information submitted to EPA without a claim of confidentiality may be disclosed to the public without inquiring whether the submitter wishes to claim confidentiality. The Agency proposes to amend §§ 122.7, 123.41 and 403.14 of this part to make those sections consistent with part 2 procedures, including changes proposed today. Specifically, the Agency is proposing to amend these sections to clarify that submitters are not prohibited from asserting CBI claims subsequent to the time of submission, but that any such late claims will be treated in accordance with § 2.203. Sections 122.7, 123.41 and 403.14 would continue to refer to the part 2 regulations as controlling the handling of CBI.

The Agency is proposing to amend § 233.3, which relates to confidentiality of information under the Section 404 State Program Regulations (part 233). In its current form, § 233.3 states that information submitted under part 233 may be claimed as confidential and that "a final determination as to that claim will be made in accordance with the procedures of 40 CFR part 2." This language could be interpreted to mean that the Agency will make a final CBI determination for all information submitted under part 233 for which a CBI claim is asserted. Such an interpretation would be inconsistent with both Agency practice and the procedures set forth in part 2. Part 2 does not require a CBI determination every time a CBI claim is submitted. Rather, information so submitted is protected as CBI until such time as the Agency has a need to disclose such information (for example, when the information is needed as part of a proceeding, or when responding to a Freedom of Information Act Request). Therefore, the Agency proposes to amend § 233.4 to conform with standard Agency CBI procedures, as set forth in part 2.

Finally, the Agency proposes to amend the discussion in § 123.42 concerning disclosure of CBI to States to include a reference to the part 2 confidentiality regulations. This change would clarify that disclosures of information under that section are subject to part 2.

U. Changes to Rules Governing Certain Information Obtained Under the Safe Drinking Water Act

The Agency is proposing amendments both to its supplemental CBI regulations at § 2.304 and to certain regulations in 40 CFR part 145 which relate to the handling of CBI under the Safe Drinking Water Act (SDWA). These changes are intended to make parts 144, 145 and 147 confidentiality provisions consistent with the provisions, including the

changes proposed today, in 40 CFR part 2.

1. Substantive Criteria Used in Confidentiality Determinations

The Agency is proposing to amend the part 2 supplemental SDWA provision (§ 2.304) to incorporate, for purposes of consistency, certain limitations on confidentiality currently provided by the SDWA regulatory provisions (§§ 144.5 and 147.2907). These sections provide that neither (1) the name and address of any permit applicant or permittee nor (2) information which deals with the existence, absence, or level of contaminants in drinking water are eligible for confidential treatment. This change to § 2.304(e) would not substantively alter the Agency's approach to CBI under the SDWA.

2. Changes to Specific Safe Drinking Water Act Regulations Under Part 145

As discussed in section B., above, the Agency is proposing to amend § 2.203 to provide that any information submitted to EPA without a claim of confidentiality may be disclosed to the public without inquiring whether the submitter wishes to claim confidentiality. The Agency proposes to amend § 145.14 of this part to make that section consistent with part 2 procedures, including those changes proposed today. Specifically, the Agency is proposing to amend § 145.14 to clarify that submitters are not prohibited from asserting CBI claims subsequent to the time of submission, but that any such late claims will be treated in accordance with § 2.203. Section 145.14 would continue to refer to the part 2 regulations as controlling the handling of CBI.

V. Changes to Rules Governing Certain Information Obtained Under the Solid Waste Disposal Act

The Agency is proposing amendments both to its supplemental CBI regulations at § 2.305 and to certain regulations in 40 CFR parts 270, 271 and 281 which relate to the handling of CBI under the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA). These changes are intended to make all RCRA confidentiality provisions consistent with the provisions, including the changes proposed today, in 40 CFR part 2.

1. Disclosure of Hazardous Waste Export Information

40 CFR 260.2 and 262.53 provide that certain information submitted in notifications of intent to export a hazardous waste will be provided to the Department of State and the appropriate authorities in a receiving country, regardless of any claims of confidentiality. Consistent with the Agency's intent to integrate the part 2 supplemental CBI regulations with regulations relating to CBI found under other Agency program regulations, EPA is proposing to amend the supplemental RCRA CBI regulation at § 2.305 to include, as a new paragraph § 2.305(f), this already existing limitation on confidentiality treatment.

2. Changes to Specific Resource Conservation and Recovery Act Regulations Under Parts 270, 271, and 281

As discussed in section B., above, the Agency is proposing to amend § 2.203 to provide that any information submitted to EPA without a claim of confidentiality may be disclosed to the public without inquiring whether the submitter wishes to claim confidentiality. The Agency proposes to amend §§ 270.12, 271.17, 271.132 and 281.43 to make those sections consistent with part 2 procedures, including the changes proposed today. Specifically, the Agency is proposing to amend these sections to clarify that submitters are not prohibited from asserting CBI claims subsequent to the time of submission, but that any such late claims will be treated in accordance with § 2.203. These sections would continue to refer to the part 2 regulations as controlling the handling of CBI.

3. Change to List of Authorities

In the authority section for part 2 and in § 2.305, section 9005 of RCRA is incorrectly cited as 42 U.S.C. 6995. The citation will be corrected to 42 U.S.C. 6991d.

W. Changes to Rules Governing Certain Information Obtained Under the Toxic Substances Control Act

The Agency is proposing amendments to its supplemental CBI regulations at § 2.306 which relate to the handling of CBI under the Toxic Substances Control Act (TSCA). These changes are intended to make all TSCA confidentiality provisions consistent with the provisions, including the changes proposed today, in 40 CFR part 2, and to clarify the scope of health and safety data under TSCA.

1. Signature of a Senior Management Official for Some Confidentiality Claims and Substantiations

EPA proposes to make several amendments to require that a senior management official sign all assertions and substantiations of confidentiality claims for information submitted pursuant to the following provisions, which constitute the core TSCA program: 40 CFR part 704, subpart A (Reporting and Recordkeeping Requirements—General Reporting and Recordkeeping Provisions for Section 8(a) Information-Gathering Rules); 40 CFR part 704, subpart C (Reporting and Recordkeeping Requirements—CAIR: Comprehensive Assessment Information Rule—General Reporting and Recordkeeping Provisions); 40 CFR part 707, subpart D (Chemical Imports and Exports—Notices of Export Under Section 12(b)); 40 CFR part 710, subpart A (Inventory Reporting Regulations—Compilation of the Inventory); 40 CFR part 710, subpart B (Inventory Reporting Regulations—Partial Updating of the Inventory Data Base); 40 CFR part 712 (Chemical Information Rules); 40 CFR part 716 (Health and Safety Data Reporting); 40 CFR part 717 (Records and Reports of Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment); 40 CFR part 720 (Premanufacture Notification); 40 CFR part 723, subpart B (Premanufacture Notice Exemptions—Specific Exemptions); 40 CFR part 750, subpart B (Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act—Interim Procedural Rules for Manufacturing Exemptions); 40 CFR part 750, subpart C (Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act—Interim Procedural Rules for Processing and Distribution in Commerce Exemptions); and 40 CFR part 790, subpart A (Procedures Governing Testing Consent Agreements and Test Rules—General Provisions).

First, EPA proposes to amend § 2.306(a) to include a definition of "senior management official". Second, EPA proposes to amend § 2.306(d) and the applicable portions of the TSCA implementing rules to require that assertions and substantiations of confidentiality in the core TSCA program be signed by such a senior management official.

The definition of senior management official is taken nearly verbatim from the implementing regulations of the Emergency Response and Community Right-To-Know Act (EPCRA), 42 U.S.C. 11001 *et seq.*, at 40 CFR 350.1. As incorporated, this definition of senior management official has been codified since 1988 and is well understood. Submitters of information pursuant to EPCRA have made the determination of who a senior management official is. Most submitters of information pursuant

to TSCA also submit information pursuant to EPCRA. The choice to use very similar language was made to simplify reporting burdens for submitters by imposing very similar reporting requirements. This will also have the effect of providing consistency between the TSCA and EPCRA programs administered by EPA which will become more important as the Agency seeks to enhance the compatibility of its data bases.

EPA believes that one situation in which submitters assert unsupportable confidentiality claims occurs when there is an inadequate review of claims at the corporate level. Individual staff and less senior management officials often lack the organizational perspective to view confidentiality claims in the context of an entire corporate policy and are unaware of the actions of other business units regarding confidentiality claims.

Based on a limited sampling of submissions pursuant to TSCA, it appears that a majority of TSCA submissions containing confidentiality claims already conform with a senior management signatures requirement. EPA believes that this wide-spread industry practice provides for needed management oversight and seeks, by this rule, to institutionalize the practice.

EPA believes that requiring all confidentiality claims and substantiations for submissions subject to this requirement to be signed by a senior management official is the most effective way to ensure that sufficient deliberation and consideration is made when claiming confidential status. As discussed in section W.3, below, EPA seeks to increase the amount of accurate TSCA derived chemical information available to the public. The Agency believes that prescribing a senior level of scrutiny will help alleviate unsupportable confidentiality claims. Also, EPA treats information claimed confidential very carefully at significant cost and expects the cooperation of industry to assure that such costs are incurred only where necessary.

Authority for a senior management official signature requirement exists in § 14(c) of the Act which states that "[a] designation * * * shall be made in writing and in such a manner as the Administrator may prescribe". This authority to impose a similar signature requirement has been previously exercised. *See, e.g.*, 40 CFR 710.32(c)(2).

2. Up-front Substantiation of Confidentiality Claims for Chemical Identity

EPA proposes to amend §§ 2.306(d), 716.55 and 717.19 to require that claims of confidentiality for chemical identity in Records and Reports of Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment, submitted pursuant to section 8(c) of TSCA, Health and Safety Data Reports, submitted pursuant to section 8(d), and notices of substantial risk, submitted pursuant to section 8(e), must be accompanied by a substantiation at the time of submission. This requirement will apply only to chemicals listed on either the public or confidential portions of the TSCA Chemical Inventory. Chemicals not on the inventory, i.e., those not available in commerce, will not be subject to this requirement.

EPA would prospectively require submitters to substantiate the confidentiality claims described above at the time of filing by responding to a series of questions. These substantiation questions are designed to address with particularity the issues generally framed by §§ 2.204(e)(4) and 2.208 which set forth, among other factors, the criteria of:

(1) What portion of the information the submitter believes is entitled to confidential treatment;

(2) The length of time for which confidential treatment is desired;

(3) Measures taken by the business to prevent undesired disclosure to others;

(4) The extent to which the information has already been disclosed to others; and

(5) Why release of the information would result in substantial harmful effects to the business' competitive position in the marketplace. 40 CFR 2.204(e)(4).

EPA has, for several years, consistently reviewed confidentiality claims for chemical identity asserted in submissions pursuant to sections 8(d) and 8(e) of TSCA. This heightened scrutiny has occurred contemporaneously with a decision by EPA's Office of Pollution Prevention and Toxics to increase the amount of accurate TSCA-derived chemical information available to the public. The major focus of these dissemination activities has been on making available health and safety data.

EPA considers chemical identity to be part of, or underlying data to, a health and safety study in health and safety data reports. *See*, 40 CFR 716.3. Furthermore, this definition of health and safety data will be formalized for all TSCA submissions (See the revision to § 2.306(a)(3) and accompanying preamble discussion, *infra*). As a result, claims of confidentiality for chemical identity in such filings are considered carefully. Nevertheless, there are situations where chemical identity in a health and safety study may be entitled to confidentiality.

Any inquiry into a confidentiality claim is a fact-specific exercise. In this particular circumstance, EPA has determined that there is a data gap when reviewing confidentiality claims for chemical identity in health and safety studies. Necessary facts regarding competitive market forces, the nature of the potential harm perceived by the submitter, the submitter's treatment of the information and other vital factors are not available to properly evaluate the claim. This requires the Agency to contact by telephone the submitter each time a claim is considered. Often, it is necessary to follow up the telephone call with a written substantiation request pursuant to 40 CFR 2.204(d)(1).

There are, however, significant problems with the current practice. First, it is inefficient for submitters. A submitter must carefully consider a confidentiality claim prior to asserting it to the Agency. The questions and issues so considered are substantially similar to the questions a submitter must answer and the issues a submitter must consider when responding to a substantiation request pursuant to 40 CFR 2.204(d)(1). When responding to such a substantiation request, the submitter is simply considering for a second time and recording the same thought processes as before. By requiring the submitter to take one look at the issues implicated by a confidentiality claim, and eliminating the duplicative two-step consideration process for submitters, the up-front substantiation requirement will be less burdensome on submitters.

Second, the current process lacks rigor, and is time-inefficient for EPA. Decisions are sometimes based on insufficient information or resources are expended gathering data which would be collected by the up-front substantiation requirement. Through imposing this new requirement, EPA seeks to improve the quality and speed of decisionmaking on confidentiality claims for chemical identity.

At the same time, EPA wishes to minimize the burden placed on submitters by the imposition of this new requirement. For this reason, the Agency has decided to impose an up-front substantiation requirement only for chemicals listed on the TSCA Chemical Inventory.

The rationale for this limitation is as follows. The intended result of the confidentiality claim review process is to make more and more useful chemical information available to the public. Chemicals which are not listed on the

TSCA Chemical Inventory may not legally enter commerce, except in extraordinarily limited circumstances. There is a lesser risk of exposure, and therefore, a lesser utility for chemical information for public information purposes, if a chemical substance is not available in commerce.

The implementation of an up-front substantiation requirement for confidentiality claims for chemical identity in the limited circumstances above is carefully sculpted to address the information needs of the Agency while minimizing the burden placed on industry.

Authority for an up-front substantiation requirement exists in the Freedom of Information Act, the Trade Secrets Act, and section 14(c) of TSCA, which states that "[a] designation * * * shall be made in writing and in such a manner as the Administrator may prescribe". (cf. discussion of sunset provisions in section F., above). This authority to impose an up-front substantiation requirement has been exercised numerous times in the past, including for confidentiality claims for chemical identity. *See, e.g.*, 40 CFR 710.38(c)(1); 40 CFR 720.85(b)(3)(iv).

3. Definition of Health and Safety Data

EPA is proposing to clarify the definition of "health and safety data" in § 2.306(a)(3) (the term "health and safety data" would be used interchangeably with "health and safety study") by adding additional language to the definition to indicate that the term encompasses not only data from a formal study but also any data pertaining to the effects of a chemical on health or the environment. The language is taken directly from the definition of "health and safety study" in 40 CFR 716.3(e), which implements health and safety data reporting pursuant to TSCA section 8(d), and in 40 CFR 720.3(k), which implements premanufacture notification procedures pursuant to TSCA section 5. EPA would include this clarification to ensure regulatory consistency under TSCA.

4. Disclosure of Health and Safety Data

TSCA section 14(b) provides that data from health and safety studies are not eligible for confidential protection unless disclosure of such data would further disclose process information or proportions of a mixture. As a means of implementing section 14(b), § 2.306(a)(3) currently defines health and safety data to exclude data whose disclosure would further disclose process information or proportions of a mixture. This definition achieves the result intended by TSCA section 14(b), that process and mixture information are not automatically exempt from confidential treatment.

However, § 2.306(a)(3) as currently written does not properly reflect the structure imposed by section 14(b). Therefore, EPA is proposing to: (1) Modify § 2.306(a)(3) to indicate that information pertaining to process and mixture data may still be health and safety data, and (2) revise § 2.306(g) (criteria for confidential treatment, redesignated in this proposal as § 2.306(h) for reasons unrelated to the discussion here) such that health and safety data whose disclosure would further disclose process information or proportions of a mixture may be eligible for confidential treatment if they meet the standard criteria for confidentiality articulated in § 2.208. No substantive change in the eligibility of such data for confidentiality is intended.

5. Reconciliation of TSCA Program-Specific Rules With Part 2 Rules

EPA proposes to incorporate various confidentiality provisions in the TSCA implementing regulations (subchapter R of title 40) into part 2. Subchapter R contains several program specific confidentiality rules tailored to the individual needs of the program. This amendment will clarify the provisions that apply to information submitted pursuant to TSCA.

Section 2.306(c) currently provides that § 2.203 of the part 2 basic rules (the basic rules are those which apply over all programs, except where otherwise indicated) applies without change to information covered by § 2.306. Section 2.203 governs procedures for asserting claims of confidentiality. Because (1) subchapter R rules which contain provisions governing confidentiality would be incorporated into § 2.306, and (2) many of these provisions differ from those in § 2.203, EPA would include a new paragraph, § 2.306(d), detailing the extent to which § 2.203 and subchapter R provisions govern assertion of CBI claims.

Similarly, those subchapter R provisions pertaining to disclosure of CBI in special circumstances (normally governed by § 2.209) would be incorporated into § 2.306(i) (currently § 2.306(h)). Section 2.306(i) would also incorporate provisions for disclosure of confidential chemical identities to *bona fide* requestors under 40 CFR parts 710, 720, 721, and 723, and for disclosure to foreign governments of export information under § 707.75(c).

Current provisions under the Pre-manufacture Notification (PMN) and Polymer Exemption Rules require reassertion and substantiation of a CBI claim for chemical identity upon filing of a Notice of Commencement (NOC). The rules also provide for expiration of the chemical identity CBI claims for the underlying PMN and Polymer Exemption Application should the NOC be filed without such reassertion and substantiation. These provisions would be incorporated into a new paragraph § 2.306(m), a sunset provision consistent with proposed § 2.216.

6. Sunset Provisions

EPA has considered proposing a sunset provision (see section F., above) for all confidentiality claims for information collected pursuant to TSCA, or for some discrete subset of claims. At this time, the Agency has decided to defer proposal of a TSCA sunset provision. EPA believes that a sunset provision is appropriate only with respect to those data collections where there is an identified need for information to be publicly available after the passage of time (or occurrence of an event). The Agency may reconsider TSCA sunset provisions after appropriate analysis and articulation of need.

In order to evaluate the issues identified above, EPA solicits comments on the following with respect to TSCA sunset provisions:

A. What information collected pursuant to TSCA would be most appropriate for application of a sunset provision? Should the sunset provision apply to all TSCA submissions of a specified type of information (e.g., all submitter identities) or only with respect to individual data collections (e.g., all submitter identities in submissions pursuant to the Partial Updating of the Inventory Data Base, 40 CFR 710.23 *et seq.*)? What information collected pursuant to TSCA would be least appropriate for application of a sunset provision?

B. How long should the period be before sunset occurs?

C. Are any mechanisms in place for industry to periodically review and relinquish confidentiality claims whose rationales for assertion have disappeared? If so, is there any vehicle for the dissemination of information no longer claimed as confidential?

X. Changes to Rules Governing Certain Information Obtained Under the Federal Insecticide, Fungicide, and Rodenticide Act

The Agency is proposing amendments to its supplemental CBI regulations at § 2.307 which relate to the handling of CBI under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These changes are intended to:

(1) Make all FIFRA confidentiality provisions consistent with the provisions, including the changes proposed today, in 40 CFR part 2;

(2) Codify procedures regarding handling of FIFRA CBI previously announced in **Federal Register** notices; and

(3) Clarify procedures for release of FIFRA CBI in emergency situations.

1. Codification of 1978 Interim Procedures

In 1978, Congress amended FIFRA to include new provisions for the treatment and release of CBI. On December 19, 1978, EPA published in the **Federal Register** a Notice of Interim Procedures for the treatment of such information (43 FR 59060). At that time, EPA stated that the interim procedures would remain in effect pending issuance of amendments to the Agency's regulations at 40 CFR part 2. EPA is proposing to amend the part 2 regulations applicable to information submitted under FIFRA to incorporate the 1978 interim procedures as permanent procedures. For more information on the rationale behind specific provisions, please refer to the Notice of Interim Procedures at 43 FR 59060.

Specifically, this proposed rule would establish procedures for handling FIFRA CBI under the following circumstances:

a. Disclosure of CBI relating to formulas of products in public hearings and in findings of fact issued by the Administrator.

The term "findings of fact" includes, but is not limited to, the process of reviewing pesticides in order to decide whether to register, reregister, or cancel those products, particularly notices published during the Special Review process under 40 CFR part 154 (formerly known as the RPAR or "rebuttable presumption against registration" process). The term also applies in cases where an inert ingredient of a pesticide is the subject of a Special Review notice.

b. Disclosure of test data relating to registered or previously registered pesticides pursuant to FIFRA.

The proposed § 2.307(g) would clarify that, pursuant to FIFRA section 10(d)(1), where safety and efficacy data (defined in proposed § 2.307(a)(5)) are submitted with regard to "a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products" (language from FIFRA section 10(d)(1)), EPA will deny any claim of confidentiality for that data unless the submitter can show that it would disclose one or more of the three types of information specifically protected by FIFRA section (10)(d)(1) (A)–(C), relating to manufacturing and quality control processes, the identity and quantity of inert ingredients, and methods of testing, detecting or measuring the quantities of inert ingredients. Where data are submitted with regard to a pesticide which is not yet registered, EPA will continue to follow the general procedures for determining confidentiality of information under the general part 2, subpart B rules. Section 2.307(a)(5) would also embody EPA's interpretation that the language in section 10(d)(1) concerning "a registered or previously registered pesticide" means that data pertaining to pesticides which have never been registered (i.e., data from applicants) is not subject to mandatory section 10(d)(1) disclosure.

c. Disclosure of FIFRA CBI to contractors.

The 1978 Notice of Interim Procedures stated that the Office of Pesticide Programs (OPP) and its contractors would follow the security procedures listed in the EPA TSCA Confidential Business Information Security Manual pending development of procedures specific to the pesticides program. Since then OPP has completed its FIFRA Information Security Manual. This document contains the procedures EPA and its contractors follow when handling FIFRA CBI and is available through the Information Services Branch of OPP. Therefore, EPA proposes that § 2.307(h)(3)(v) state that contractors who are allowed access to FIFRA CBI will be required to follow the security procedures detailed in that manual.

d. Disclosure of data to foreign or multinational pesticide producers.

The 1978 amendments to FIFRA included a provision, section 10(g), which prohibits EPA from providing data submitted by a registrant or an applicant for registration (without the submitter's consent) to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States, or to any other person who intends to deliver such data to any such foreign or multinational entity. In addition, FIFRA section 10(g) compels the Administrator to require that every person requesting data affirm that such person does not seek access to the data in order to deliver it or offer it for sale to any foreign or multinational entity described above, and that such person will not purposefully deliver it nor negligently cause it to be delivered to any such entity. This proposed rule would codify the procedures by which EPA implements this section and the affirmation which must be made by all persons seeking access to data submitted by registrants or applicants under FIFRA.

The text of FIFRA section 10(g) uses the terms "information" and "data" interchangeably. EPA has historically interpreted this section to apply only to test data submitted by registrants and applicants for registration. This is because section 10(g) was designed to prevent companies from obtaining proprietary data from EPA under FOIA and FIFRA section 10(d)(1) and using it to gain market entry in foreign countries without contributing to the costs of developing the data, as FIFRA section 3(c)(1)(F) requires of domestic market entrants. The term "information" could be read to include items which EPA routinely makes available such as registration applications, product labeling, and general offers to pay data compensation. Because EPA believes that Congress intended to restrict foreign companies' access to registration data, EPA interprets section 10(g) to apply only to test data.

On September 24, 1985, EPA issued Class Determination 3–85, stating that reviews of data submitted by applicants or registrants which were prepared by EPA personnel or under an EPA-funded contract and which do not reveal the full methodology and complete results of the study, test, or experiment, and all explanatory information necessary to understand the methodology or interpret the results are not subject to FIFRA section 10(g). Class Determination 3–85 noted that section 10(g) "is intended to prevent a person from obtaining, under FIFRA, data generated at another person's expense and then using the data to obtain the approval of another country's government to manufacture, sell, or use pesticides in that country * * * Disclosure of EPA reviews of data (provided that they are truly reviews, and not essentially complete reports) will not be useful in obtaining approvals by governments of other countries. To the extent that such a country requires data to evaluate the request, it is unlikely to be satisfied with a review of data conducted by EPA; to the extent that such a country is willing to accept an EPA review in lieu of data, it is just as likely to accept other readily available information indicating EPA's position, such as evidence that EPA has registered the product." EPA proposes to codify this interpretation of FIFRA section 10(g) in § 2.307(i)(1).

Class Determination 3–85 also stated that reviews of safety and efficacy data which contain neither the three types of

information specifically protected by FIFRA section (10)(d)(1) (A)–(C) nor unpublished information concerning the production, distribution, sale, or inventories of a pesticide are not eligible for confidential treatment. This would be codified in proposed § 2.307(k)(2).

2. Incorporation of FIFRA Program Provisions Regarding CBI

In addition to the procedures proposed above, EPA is proposing to amend the part 2 regulations to reference various regulations promulgated under FIFRA at 40 CFR parts 152, 154, 155, and 158, which contain specific provisions regarding CBI submitted under those regulations. This amendment would not change the substance of those provisions, but would merely incorporate them into § 2.307. These provisions pertain mainly to assertion of business confidentiality claims when submitting particular types of information; also incorporated (in § 2.307(k)(1)) is a provision currently in § 152.119(b), governing public inspection of materials submitted to comply with section 3(c)(1)(D) of FIFRA.

In addition, the Agency is proposing to add a new paragraph § 2.307(j), regarding designation by a business of an addressee for notices and inquiries. This provision would incorporate the requirements of 40 CFR 152.50(b) (2) and (3) for businesses which are registrants or applicants for registration of a pesticide. For parties other than registrants or applicants, § 2.213(a) would still apply.

3. Release in Emergency Situations

EPA is proposing two amendments intended to clarify what personnel could be allowed access to CBI in the event of an emergency under § 2.307(h)(2). First, EPA proposes to define the term "qualified persons" to include any person whose presence or services are required for the prevention or mitigation of imminent harm to persons, property, or the environment, and who requires access to confidential information in order to perform his or her duties in that capacity. Second, EPA proposes to clarify that the term "governmental agencies" in that section include federal, State, and local governments.

4. Pesticide Export Policy

On January 12, 1990 EPA published a **Federal Register** notice (55 FR 1261) indicating the Agency's position that the producer identity, exporter identity, name of unregistered pesticide, and name of active ingredient in export notifications under FIFRA section 17(a)(2) were not entitled to confidentiality. On April 25, 1991 EPA issued Class Determination 1–91, which provided that the identities of importing countries in purchaser acknowledgement statements were not entitled to confidentiality. This Class Determination was published in the February 18, 1993 policy statement governing exported pesticides (58 FR 9062). That policy statement also refined the Agency's position with respect to confidentiality of data concerning research and development products, stating that these products may in some cases be eligible for confidential treatment. EPA proposes to codify this position in § 2.307(g)(2). For details concerning this position, see 55 FR 1261.

Executive Order 12866

Under Executive Order 12866 (58 FR 51735 (October 4, 1993)) the Agency must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) has been prepared by EPA (ICR No. 1667.01) and a copy may be obtained from Sandy Farmer, Information Policy Branch (2136); U.S. Environmental Protection Agency; 401 M Street, SW., Washington, DC 20460 or by calling (202) 260–2740.

The public reporting burden for this collection of information is estimated to average 3.3 hours per response, including the time for rule familiarization, gathering necessary data, drafting a substantiation, submitting the substantiation, and recordkeeping for the information collection. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch (2136); U.S. Environmental Protection Agency; 401 M Street, SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator certifies that this rule would not have a significant economic impact on a substantial number of small entities. The Act requires identification of those regulations which are likely to have a "significant economic impact on a substantial number of small entities," i.e., small governments, small businesses, and small non-profit organizations. Under the requirements of the Act, such regulations must be subjected to a regulatory flexibility analysis. This analysis must address the likely economic impacts on small entities and must consider any significant alternatives to the rule which accomplish the objectives of applicable statutes and which minimize any significant economic impact of the rulemaking on small entities. In April 1992, EPA adopted a new policy which goes beyond the minimum requirements of the Act (this policy applies to rulemaking initiated after April 8, 1992). For rules subject to this new policy, EPA will perform a regulatory flexibility analysis if the rule is likely to have any economic impact on any small entity.

EPA has performed an Initial Regulatory Flexibility Analysis for the changes in Agency confidentiality regulations proposed here. It is available for comment from Donald A. Sadowsky, General and Information Law Division (2379), Office of General Counsel, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The Agency has identified as an impact

the reporting burden discussed in the Information Collection Request (see Paperwork Reduction Act discussion above), deriving from (1) the requirement (discussed in section B.2., above) to substantiate claims of confidentiality asserted for an entire document (as opposed to portions of the document), and (2) new proposed TSCA-specific signature and up-front substantiation requirements (discussed in sections W.1 and W.2, above). The estimated burdens for respondents would be $347.53 (general provisions), $157.36 (TSCA-specific signature), and $212.47 (TSCA-specific up-front substantiation). EPA estimates that 285 respondents per year would incur the burden pertaining to general provisions, 5,313 for TSCA-specific signature, and 360 for TSCA-specific up-front substantiation. An unknown number of these respondents would be small entities. The Agency made the burden for the general provisions as low as possible, choosing not to require respondents to answer the full series of questions posed when the Agency must make a determination of confidentiality when information is requested under FOIA. Any submitter may avoid this burden completely by merely identifying which portions of the submitted document should be protected as confidential. With respect to the TSCA-specific provisions, flexibility in the TSCA-specific regulations exists for small entities because small entities are largely exempt from TSCA reporting requirements.

List of Subjects

40 CFR Part 2

Administrative practice and procedure, Confidential business information, Courts, Freedom of information, Government employees.

40 CFR Part 57

Administrative practice and procedure, Air pollution control, Metals, Reporting and recordkeeping requirements, Research, Sulfur oxides.

40 CFR Part 85

Confidential business information, Imports, Labeling, Motor vehicle pollution, Reporting and recordkeeping requirements, Research, Warranties.

40 CFR Part 86

Administrative practice and procedure, Confidential business information, Labeling, Motor vehicle pollution, Reporting and recordkeeping requirements.

40 CFR Part 122

Administrative practice and procedure, Confidential business information, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 123

Administrative practice and procedure, Confidential business information, Hazardous substances, Indians—lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 145

Confidential business information, Indians—lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 233

Administrative practice and procedure, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 260

Administrative practice and procedure, Confidential business information, Hazardous waste.

40 CFR Part 270

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 271

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 281

Administrative practice and procedure, Hazardous substances, Insurance, Intergovernmental relations, Oil pollution, Reporting and recordkeeping requirements, Surety bonds, Water pollution control, Water supply.

40 CFR Part 350

Administrative practice and procedure, Chemicals, Confidential business information, Disaster assistance, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

40 CFR Part 403

Confidential business information, Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control.

40 CFR Part 704

Environmental protection, Chemicals, Confidential business information, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Part 707

Environmental protection, Chemicals, Exports, Hazardous substances, Imports, Confidential business information, Reporting and recordkeeping requirements.

40 CFR Part 710

Environmental protection, Chemicals, Inventory, Partial Updating of the inventory data base, Confidential business information, Reporting and recordkeeping requirements.

40 CFR Part 712

Environmental protection, Chemicals, Confidential business information, Reporting and recordkeeping requirements.

40 CFR Part 716

Environmental protection, Chemicals, Hazardous substances, Health and safety, Confidential business information, Reporting and recordkeeping requirements.

40 CFR Part 717

Environmental protection, Chemicals, Confidential business information, Reporting and recordkeeping requirements, Significant adverse reactions.

40 CFR Part 720

Environmental protection, Chemicals, Premanufacture notification, Hazardous materials, Confidential business information, Reporting and recordkeeping requirements.

40 CFR Part 723

Environmental protection, Chemicals, Premanufacture notification, Hazardous materials, Confidential business information, Reporting and recordkeeping requirements.

40 CFR Part 750

Administrative practice and procedure, Chemicals, Confidential business information, Reporting and recordkeeping requirements.

40 CFR Part 790

Environmental protection, Chemicals, Testing, Hazardous substances, Confidential business information, Reporting and recordkeeping requirements.

Dated: November 3, 1994.

Carol M. Browner,

Administrator.

Therefore 40 CFR parts 2, 57, 85, 86, 122, 123, 145, 233, 260, 270, 271, 281, 350, 403, 704, 707, 710, 712, 716, 717, 720, 723, 750 and 790 are proposed to be amended as follows:

PART 2—[AMENDED]

The authority citation for part 2 is revised to read as follows:

Authority: 5 U.S.C. 301, 552 (as amended), 553; secs. 114, 206, 208, 301, and 307, Clean Air Act, as amended (42 U.S.C. 7414, 7525, 7542, 7601, 7607); secs. 308, 501 and 509(a), Clean Water Act, as amended (33 U.S.C. 1318, 1361, 1369(a)); sec. 13, Noise Control Act of 1972 (42 U.S.C. 4912); secs. 1445 and 1450, Safe Drinking Water Act (42 U.S.C. 300j–4, 300j–9); secs. 2002, 3007, and 9005, Solid Waste Disposal Act, as amended (42 U.S.C. 6912, 6927, 6991d); secs. 8(c), 11, 12(b), and 14, Toxic Substances Control Act (15 U.S.C. 2607(c), 2610, 2611(b), 2613); secs. 10, 12, and 25, Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136h, 136j, 136w); sec. 408(f), Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 346(f)); secs. 104(f) and 108, Marine Protection, Research and Sanctuaries Act of 1972 (33 U.S.C. 1414(f), 1418); secs. 104, 115, Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (42 U.S.C. 9604, 9615); sec. 505, Motor Vehicle Information and Cost Savings Act, as amended (15 U.S.C. 2005).

2. Section 2.111 is amended by revising paragraph (a)(4) to read as follows:

§ 2.111 Action by office responsible for responding to request.

(a) * * *

(4) If any located records contain business information, as defined in § 2.201(c), comply with subpart B of this part. However, if the request encompasses information claimed as business confidential pursuant to subpart B of this part but is silent on whether the requestor desires information subject to a claim of confidentiality, the office shall presume that such information is excluded from the scope of the request, and need not take the actions required by § 2.204(d). Nonetheless the office shall provide the requestor with a description of those records claimed as confidential which would have been within the scope of the request had the presumption in this paragraph not been applied;

* * * * *

3. Section 2.113 is amended by revising paragraph (a)(1) to read as follows:

§ 2.113 Initial denial of requests.

(a) * * *

(1) A statutory provision, provision of this part, or court order requires that the information not be disclosed (information withheld pursuant to section 10(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136h(g)) will be handled pursuant to procedures in § 2.307(j) of this part);

* * * * *

4. Part 2, subpart B is revised to read as follows:

Subpart B—Confidential Business Information.

Sec.

§ 2.201 Definitions.

For the purposes of this subpart:

(a) *Person* means an individual, partnership, corporation, association, or other public or private organization or legal entity, including Federal, State or local governmental bodies and agencies and their employees.

(b) *Business* means any person engaged in a business, trade, employment, calling or profession, whether or not all or any part of the net earnings derived from such engagement by such person inure (or may lawfully inure) to the benefit of any private shareholder or individual.

(c) *Business information* (sometimes referred to simply as information) means any information which pertains to the interests of any business, which was developed or acquired by that business, and (except where the context otherwise requires) which is possessed by EPA in recorded form.

(d) *Affected business* means, with reference to an item of business information, a business which has asserted (and not waived or withdrawn) a business confidentiality claim covering the information, or a business which could be expected to make such a claim if it were aware that disclosure of the information to the public was proposed.

(e) *Reasons of business confidentiality* include the concept of trade secrecy and other related legal concepts which give (or may give) a business the right to preserve the confidentiality of business information and to limit its use or disclosure by others in order that the business may obtain or retain business advantages it derives from its rights in the information. The definition is meant

to encompass any concept which authorizes a Federal agency to withhold business information under 5 U.S.C. 552(b)(4), as well as any concept which requires EPA to withhold information from the public for the benefit of a business under 18 U.S.C. 1905 or any of the various statutes cited in §§ 2.301 through 2.311.

(f) [*Reserved*]

(g) *Information which is available to the public* is information in EPA's possession which EPA will furnish to any member of the public upon request and which EPA may make public, release or otherwise make available to any person whether or not its disclosure has been requested.

(h) *Business confidentiality claim* (or, simply, *claim*) means a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality, or a request for a determination that such information is entitled to such treatment.

(i) [*Reserved*]

(j) *Recorded* means written or otherwise registered in some form for preserving information, including such forms as drawings, photographs, videotape, sound recordings, punched cards, and computer tape or disk.

(k) [*Reserved*]

(l) *Administrator, Regional Administrator, General Counsel, Regional Counsel,* and *Freedom of Information Officer* mean the EPA officers or employees occupying the positions so titled (or designated to act in such position).

(m) *EPA office* means any organizational element of EPA, at any level or location. (The terms EPA office and EPA legal office are used in this subpart for the sake of brevity and ease of reference. When this subpart requires that an action be taken by an EPA office or by an EPA legal office, it is the responsibility of the officer or employee in charge of that office to take the action or ensure that it is taken.)

(n) *EPA legal office* means the EPA General Counsel, any EPA office over which the General Counsel exercises supervisory authority, and the various Offices of Regional Counsel. (See paragraph (m) of this section.)

(o) A *working day* is any day on which Federal government offices are open for normal business. Saturdays, Sundays, and official Federal holidays are not working days; all other days are.

§ 2.202 Applicability of subpart; priority where provisions conflict; records containing more than one kind of information.

(a) Sections 2.201 through 2.216 establish basic rules governing business confidentiality claims, the handling by EPA of business information which is or may be entitled to confidential treatment, and determinations by EPA of whether information is entitled to confidential treatment for reasons of business confidentiality.

(b) Various statutes (other than 5 U.S.C. 552) under which EPA operates contain special provisions concerning the entitlement to confidential treatment of information gathered under such statutes. Sections 2.301 through 2.311 prescribe rules for treatment of certain categories of business information obtained under the various statutory provisions. Paragraph (b) of each of those sections should be consulted to determine whether any of those sections applies to the particular information in question.

(c) The basic rules of §§ 2.201 through 2.216 govern except to the extent that they are modified or supplanted by the special rules of §§ 2.301 through 2.311. In the event of a conflict between the provisions of the basic rules and those of a special rule which is applicable to the particular information in question, the provision of the special rule shall govern.

(d) If two or more of the sections containing special rules apply to the particular information in question, and the applicable sections prescribe conflicting special rules for the treatment of the information, the rule which provides greater or wider availability to the public of the information shall govern.

(e) For most purposes, a document or other record may usefully be treated as a single unit of information, even though in fact the document or record is comprised of a collection of individual items of information. However, in applying the provisions of this subpart, it will often be necessary to separate the individual items of information into two or more categories, and to afford different treatment to the information in each such category. The need for differentiation of this type may arise, e.g., because a business confidentiality claim covers only a portion of a record, or because only a portion of the record is eligible for confidential treatment. EPA offices taking action under this subpart must be alert to this problem.

(f) In taking actions under this subpart, EPA offices are not required to obtain the affected business' consent to disclosure of useful portions of records while protecting the information which is or may be entitled to confidentiality (e.g., by withholding such portions of a record as would identify a business, or by disclosing data in the form of industry-wide aggregates, multi-year averages or totals, or some similar form). However, when disclosing portions of a record, offices must ensure that the portions disclosed do not contain information claimed as confidential under this subpart. Offices may not disclose aggregated numerical data except where the aggregate was calculated using a methodology on which an EPA legal office has been consulted.

(g) This subpart does not apply to questions concerning entitlement to confidential treatment or information which concerns an individual solely in his personal, as opposed to business, capacity.

§ 2.203 Notice to be included in EPA requests, demands, and forms; method of asserting business confidentiality claim; effect of failure to assert claim at time of submission.

(a) *Notice to be included in certain requests and demands for information, and in certain forms.* Whenever an EPA office makes a written request or demand that a business furnish information which, in the office's opinion, is likely to be regarded by the business as entitled to confidential treatment under this subpart, or whenever an EPA office prescribes a form for use by businesses in furnishing such information, the request, demand, or form shall include or enclose a notice which—

(1) States that the business may, if it desires, assert a business confidentiality claim covering part or all of the information, in the manner described by paragraph (b) of this section, and that information covered by such a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in this subpart;

(2) States that if no such claim accompanies the information when it is received by EPA, it may be made available to the public without further notice to the business; and

(3) Furnishes a citation of the location of this subpart in the Code of Federal Regulations.

(b) *Method and time of asserting business confidentiality claim.* (1) A business which is submitting information to EPA may assert a business confidentiality claim covering the information by placing on (or attaching to) the information, at the time it is submitted to EPA, a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as trade secret, proprietary, or company confidential. Allegedly confidential portions of otherwise non-confidential documents

must be clearly identified by the business, and may be submitted separately to facilitate identification and handling by EPA. If the business desires confidential treatment only until a certain date or until the occurrence of a certain event, the notice should so state.

(2) A confidentiality claim asserted on or after [insert effective date of final rule] which does not identify those portions of the document which are allegedly confidential will not be recognized by EPA unless the claim is accompanied by a substantiation of why the entire document (as opposed to portions of the document) meets the criteria for confidentiality set forth in § 2.208. Section 2.205(c) applies to substantiations submitted under this paragraph.

(3) Where a specific submission to EPA is claimed as confidential and is subject to an EPA regulation which requires that documentation substantiating a confidentiality claim (addressing or expanding upon the criteria for confidentiality in § 2.208) be submitted to the Agency at the same time the business submits the information claimed to be confidential, and a business fails to provide the same, EPA will not recognize the confidentiality claim.

(c) *Effect of failure to assert claim at time of submission of information.* (1) Where information received by EPA is unaccompanied by a business confidentiality claim, the inquiry to the business required by § 2.204(c)(2) need not be made provided that EPA does not have substantial reason to believe that disclosure would result in competitive harm if either—

(i) The information was submitted by a business to EPA before [insert effective date of final rule] in response to an EPA request or demand (or on an EPA-prescribed form) which contained the substance of the notice required by paragraph (a) of this section; or

(ii) The information was submitted by a business to EPA on or after [insert effective date of final rule].

(2) If a claim covering the information is received after the information itself is received, EPA will make such efforts as are administratively practicable to associate the late claim with copies of the previously-submitted information in EPA files (see § 2.204(c)(1)). However, EPA cannot assure that such efforts will be effective, in light of the possibility of prior disclosure or widespread prior dissemination of the information.

§ 2.204 Initial action by EPA office.

(a) *Situations requiring action.* This section prescribes procedures to be used by EPA offices in making initial determinations of whether business information is entitled to confidential treatment for reasons of business confidentiality. Action shall be taken under this section whenever an EPA office:

(1) Learns that it is responsible for responding to a request under 5 U.S.C. 552 for the release of business information; in such a case, the office shall issue an initial determination within the period specified in § 2.112. However, if pursuant to § 2.111(a)(4) the request is presumed not to include information claimed as confidential, the office shall take those actions required by paragraph (c) of this section to determine the existence of confidentiality claims, but shall not take action under paragraph (b) or (d) of this section;

(2) Desires to determine whether business information in its possession is entitled to confidential treatment, even though no request for release of the information has been received; or

(3) Determines that it is likely that EPA eventually will be requested to disclose the information at some future date and thus will have to determine whether the information is entitled to confidential treatment. In such a case this section's procedures should be initiated at the earliest practicable time, in order to increase the time available for preparation and submission of comments and for issuance of determinations, and to make easier the task of meeting response deadlines if a request for release of the information is later received under 5 U.S.C. 552.

(b) *Previous confidentiality determination.* The EPA office shall first ascertain whether there has been a previous determination, issued by a Federal court or by an EPA legal office acting under this subpart, as to whether the information in question is entitled to confidential treatment for reasons of business confidentiality. The office shall also take into account any determination of confidentiality (of which the office is aware) issued by a State or local government entity.

(1) If a determination issued by a Federal court or by an EPA legal office holds that the information is entitled to confidential treatment, the EPA Office shall furnish any person whose request for the information is pending under 5 U.S.C. 552 an initial determination (see §§ 2.111 and 2.113) that the information has previously been determined to be entitled to confidential treatment, and that the request is therefore denied. The office shall furnish such person the appropriate case citation or EPA determination. If the EPA office believes that a previous determination which was issued by an EPA legal office may be improper or no longer valid, the office shall so inform the EPA legal office, which shall consider taking action under § 2.205(h).

(2) If a determination issued by a Federal court or by an EPA legal office holds that the information is not entitled to confidential treatment, the EPA office may proceed pursuant to § 2.204(d)(2).

(3) If a determination issued by a Federal agency or by a State or local government entity holds that the information is not entitled to confidential treatment, and the information is available to the public from the State or local government entity, the EPA office may proceed pursuant to § 2.204(d)(2).

(4) With respect to all information not known to be covered by any of paragraphs (b) (1)–(3) of this section, the EPA office shall take action under paragraph (c) of this section.

(c) *Determining existence of business confidentiality claims.*

(1) Whenever action under this paragraph is required by paragraph (a)(1) or (b)(4) of this section, the EPA office shall examine the information and the office's records to determine which businesses, if any, are affected businesses (see § 2.201(d)), and to determine which businesses, if any, have asserted business confidentiality claims which remain applicable to the information. If any business is found to have asserted an applicable claim (and the request, if any, under 5 U.S.C. 552 has not been presumed to exclude information claimed as confidential pursuant to § 2.111(a)(4)), the office shall take action under paragraph (d) of this section with respect to each such claim.

(2)(i) If the examination conducted under paragraph (c)(1) of this section discloses the existence of any business which, although it has not asserted a claim, might be expected to assert a claim if it knew EPA proposed to disclose the information, the EPA office shall contact a responsible official of each such business to learn whether the business asserts a claim covering the information. However, unless EPA has substantial reason to believe that disclosure of the information would result in competitive harm, no such inquiry need be made—

(A) To any business which failed to assert a claim covering the information when responding to an EPA request or demand, or supplying information on an EPA form, which contained the substance of the statements prescribed by § 2.203(a);

(B) To any business which otherwise failed to assert a claim covering the information after being informed by EPA that such failure could result in disclosure of the information to the public;

(C) To any business which has otherwise waived or withdrawn a claim covering the information; or

(D) With respect to information submitted on or after [insert effective date of final rule].

(ii) If a request for release of the information under 5 U.S.C. 552 is pending at the time inquiry is made under this paragraph (c)(2), the inquiry shall be made by telephone or equally prompt means, and the responsible official contacted shall be informed that any claim the business wishes to assert must be brought to the EPA office's attention no later than the close of business on the third working day after such inquiry.

(iii) A record shall be kept of the results of any inquiry under this paragraph (c)(2) of this section. If any business makes a claim covering the information, and the request, if any, under 5 U.S.C. 552 has not been presumed to exclude information claimed as confidential pursuant to § 2.111(a)(4)), the EPA office shall take further action under paragraph (d) of this section.

(3) If, after the examination under paragraph (c)(1) of this section, and after any inquiry made under paragraph (c)(2) of this section, the EPA office knows of no claim covering the information and the time for response to any inquiry has passed, the information shall be treated for purposes of this subpart as not entitled to confidential treatment.

(d) *Preliminary determination.* Whenever action under this paragraph is required by paragraph (c) (1) or (2) of this section on any business' claim, the EPA Office shall make a determination with respect to each such claim. Each determination shall be made after consideration of the provisions of § 2.203, the applicable substantive criteria in § 2.208 or elsewhere in this subpart, and any previously-issued determinations under this subpart which are applicable.

(1) If, in connection with any business' claim, the office determines that the information may be entitled to confidential treatment, the office shall—

(i) Furnish the notice of opportunity to submit comments prescribed by paragraph (e) of this section to each business which is known to have asserted an applicable claim and which has not previously been furnished such notice with regard to the information in question;

(ii) Furnish, to any person whose request for release of the information is pending under 5 U.S.C. 552, a determination (in accordance with § 2.113) that the information may be entitled to confidential treatment under this subpart and 5 U.S.C. 552(b)(4), that further inquiry by EPA pursuant to this subpart is required before a final determination on the request can be issued, that the person's request is therefore initially denied, and that after further inquiry a final determination will be issued by an EPA legal office; and

(iii) Refer the matter to the appropriate EPA legal office, furnishing the information required by paragraph (f) of this section after the time has elapsed for receipt of comments from the affected business.

(2) If, in connection with all applicable claims, the office determines that the information clearly is not entitled to confidential treatment, the office shall take the actions required by § 2.205(f). However, if a business has previously been furnished notice under § 2.205(f) with respect to the same information, no further notice need be furnished to that business. A copy of each notice furnished to a business under this paragraph (d)(2) and § 2.205(f) shall be forwarded promptly to the appropriate EPA legal office.

(3)(i) A business has waived its confidentiality claim if—

(A) The EPA office designated to receive the business' comments (pursuant to paragraph (d)(1)(i)) has not received those comments within the specified time, including any approved extension, (after making appropriate inquiry on whether the comments were lost in transmission) under § 2.205(b); and

(B) The business was notified in writing at the time comments were solicited that failure to submit timely comments would be construed as a waiver of the business' claim.

(ii) If, after application of the preceding paragraph (i), no confidentiality claim applies to the information, the office shall determine that the information is not entitled to confidential treatment under this subpart and, subject to § 2.210, is available to the public and may be disclosed without notice to any business.

(e) *Notice to affected businesses; opportunity to comment.* (1) Whenever required by paragraph (d)(1) of this section, the EPA office shall promptly furnish each business a written notice stating that EPA is determining under this subpart whether the information is entitled to confidential treatment, and affording the business an opportunity to comment. The notice shall be furnished by certified mail (return receipt requested), by personal delivery, or by other means which allows verification of the fact and date of receipt. The notice shall state the address of the office to which the business' comments shall be addressed (the EPA office furnishing the notice, unless the General Counsel has directed otherwise), the time allowed for comments, and the method for requesting a time extension under § 2.205(b)(2). The notice shall further state that EPA will construe a business' failure to furnish timely comments as a waiver of the business' claim.

(2) If action under this section is occasioned by a request for the information under 5 U.S.C. 552, the period for comments shall be 15 working days after the date of the business' receipt of the written notice. In other cases, the EPA office shall establish a reasonable period for comments (not less than 15 working days after the business' receipt of the written notice). The time period for comments shall be considered met if the business' comments are postmarked or hand delivered to the office designated in the notice by the date specified. In all cases, the notice shall call the business' attention to the provisions of § 2.205(b).

(3) The written notice required by paragraph (e)(1) of this section shall invite the business' comments on the following points (subject to paragraph (e)(4) of this section):

(i) The portions of the information which are alleged to be entitled to confidential treatment;

(ii) The period of time for which confidential treatment is desired by the business (e.g., until a certain date, until the occurrence of a specified event, or permanently);

(iii) The purpose for which the information was furnished to EPA and the approximate date of submission, if known;

(iv) Whether a business confidentiality claim accompanied the information when it was received by EPA;

(v) Measures taken by the business to guard against undesired disclosure of the information to others;

(vi) The extent to which the information has been disclosed to others, and the precautions taken in connection therewith;

(vii) Pertinent confidentiality determinations, if any, by EPA or other Federal agencies, as well as by State and local governmental entities, and a copy of any such determination, or reference to it, if available;

(viii) Whether the business asserts that disclosure of the information would be likely to result in substantial harmful effects on the business' competitive position, and if so, what those harmful effects would be, why they should be viewed as substantial, and an explanation of the causal relationship between disclosure and such harmful effects; and

(ix) Whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.

(4)(i) To the extent that the EPA office already possesses the relevant facts, the notice need not solicit responses to the matters addressed in paragraph (e)(3) (i) through (ix) of this section, although the notice shall request confirmation of EPA's understanding of such facts where appropriate.

(ii) If the EPA office believes that the information submitted to EPA was submitted voluntarily, the notice need not solicit responses to the matters addressed in paragraph (e)(3)(viii) of this section. If, upon examination of the information provided to an EPA legal office pursuant to paragraph (f) of this section, the legal office believes that the information was not voluntarily submitted, the legal office shall solicit responses to the matters addressed in paragraph (e)(3)(viii) of this section, pursuant to the procedures of this paragraph (e).

(5) The notice shall refer to § 2.205(c) and shall include the statement prescribed by § 2.203(a).

(f) *Materials to be furnished to EPA legal office.* When a matter is referred to an EPA legal office under paragraph (d)(1) of this section, the EPA office taking action under this section shall forward promptly to the EPA legal office the following items:

(1) A copy of the information in question, or (where the quantity or form of the information makes forwarding a copy of the information impractical) representative samples, a description of the information, or both;

(2) A description of the circumstances and date of EPA's acquisition of the information;

(3) The name, address, and telephone number of the EPA employee(s) most familiar with the information;

(4) The name, address and telephone number of each business which asserts an applicable business confidentiality claim;

(5) A copy of each applicable claim (or the record of the assertion of the claim), and a description of when and how each claim was asserted;

(6) Comments concerning each business' compliance or noncompliance with applicable requirements of § 2.203;

(7) A copy of any request for release of the information pending under 5 U.S.C. 552;

(8) A copy of the business' comments on whether the information is entitled to confidential treatment;

(9) The office's comments concerning the appropriate substantive criteria under this subpart, and information the office possesses concerning the information's entitlement to confidential treatment; and

(10) Copies of other correspondence or memoranda which pertain to the matter.

§ 2.205 Final confidentiality determination by EPA legal office.

(a) *Role of EPA legal office.* (1) The appropriate EPA legal office (see paragraph (i) of this section) is responsible for making the final administrative determination of whether or not business information covered by a business confidentiality claim is entitled to confidential treatment under this subpart.

(2) When a request for release of the information under 5 U.S.C. 552 is pending, the EPA legal office's determination shall serve as the final determination on appeal from an initial denial of the request.

(i) If the initial denial was issued under § 2.204(b)(1), a final determination by the EPA legal office is necessary only if the requestor has actually filed an appeal.

(ii) If the initial denial was issued under § 2.204(d)(1), however, the EPA legal office shall issue a final determination in every case, unless the request has been withdrawn. (Initial denials under § 2.204(d)(1) are of a procedural nature, to allow further inquiry into the merits of the matter, and a requestor is entitled to a decision on the merits.) If an appeal from such a denial has not been received by the EPA Freedom of Information Officer on the tenth working day after issuance of the denial, the matter shall be handled as if an appeal had been received on that day, for purposes of establishing a schedule for issuance of an appeal decision under § 2.117 of this part.

(b) *Comment period; extensions.* (1) Each business which has been furnished the notice and opportunity to comment prescribed by §§ 2.204(d)(1) and 2.204(e) shall furnish its comments to the office specified in the notice in time to be postmarked or hand delivered to that office not later than the date specified in the notice (or the date established in lieu thereof under this section).

(2) The period for submission of comments may be extended if, before the comments are due, a request for an extension of the comment period is made by the business and approved by the EPA legal office. Except in extraordinary circumstances, the EPA legal office will not approve such an extension without the consent of any person whose request for release of the information under 5 U.S.C. 552 is pending.

(3) The period for submission of comments by a business may be shortened in the manner described in paragraph (g) of this section.

(4) If a business' comments have not been received by the specified EPA office by the date they are due (including any approved extension), that office shall promptly inquire whether the business has complied with paragraph (b)(1) of this section. If the business has complied with paragraph (b)(1) of this section but the comments have been lost in transmission, duplicate comments shall be requested.

(c) *Confidential treatment of comments from business.* If information is submitted to EPA by a business as part of its comments under this section or as part of a substantiation pursuant to § 2.203(b)(2), pertains to the business' claim, is not otherwise possessed by EPA, and is marked when received in accordance with § 2.203(b)(1), it will be regarded by EPA as entitled to confidential treatment and will not be disclosed by EPA without the business' consent, unless its disclosure is duly ordered by a Federal court, notwithstanding other provisions of this subpart to the contrary.

(d) *Types of final determinations; matters to be considered.* (1) The EPA legal office shall consider each business' claim and comments (provided that the claim is not waived or otherwise rendered ineffective by any provision of this subpart), the various provisions of this subpart, any previously-issued determinations under this subpart which are pertinent, the materials furnished it under § 2.204(f), and such other materials as it finds appropriate. With respect to each claim, the office shall determine whether or not the information is entitled to confidential treatment for the benefit of the business that asserted the claim, and the period of any such entitlement (e.g., until a certain date, until the occurrence of a specified event, or permanently), and shall take further action under paragraph (e) or (f) of this section, as appropriate.

(2) Whenever the claims of two or more businesses apply to the same information, the EPA legal office shall take action appropriate under the particular circumstances to protect the interests of all persons concerned (including any person whose request for the information is pending under 5 U.S.C. 552).

(e) *Determination that information is entitled to confidential treatment.* If the EPA legal office determines that the information is entitled to confidential treatment for the full period requested by the business which made the claim, EPA shall maintain the information in confidence for such period, subject to paragraph (h) of this section, § 2.209, and the other provisions of this subpart which authorize disclosure in specified circumstances, and the office shall so inform the business. If any person's request for the release of the information is then pending under 5 U.S.C. 552, the EPA legal office shall issue a final determination denying that request.

(f) *Determination that information is not entitled to confidential treatment; notice; waiting period; release of information.* (1) Notice of denial (or partial denial) of a business confidentiality claim, in the form prescribed by paragraph (f)(2) of this section, shall be furnished—

(i) By the EPA office taking action under § 2.204, to each business on behalf of which a claim has been made, whenever § 2.204(d)(2) requires such notice; and

(ii) By the EPA legal office taking action under this section, to each business which has asserted a claim applicable to the information and which has furnished timely comments under paragraph (b) of this section, whenever the EPA legal office determines that the information is not entitled to confidential treatment under this subpart for the benefit of the business, or determines that the period of any entitlement to confidential treatment is shorter than that requested by the business.

(2) The notice prescribed by paragraph (f)(1) of this section shall be written, and shall be furnished by certified mail (return receipt requested), by personal delivery, or by other means which allows verification of the fact of receipt and the date of receipt. The notice shall state the basis for the determination, that it constitutes final agency action concerning the business confidentiality claim, and that such final agency action may be subject to judicial review under Chapter 7 of Title 5, United States Code. With respect to EPA's implementation of the determination, the notice shall state that (subject to § 2.210) EPA will make the information available to the public on the tenth working day after the date of the business' receipt of the written notice (or on such later date as is established in lieu thereof by the EPA legal office under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business' commencement of an action in a Federal court to obtain judicial review of the determination and to obtain preliminary injunctive relief against disclosure. The notice shall further state that if such an action is timely commenced, EPA may nonetheless make the information available to the public (in the absence of an order by the court to the contrary) once the court has denied a motion for a preliminary injunction in the action or has otherwise upheld the EPA determination, or whenever it appears to the EPA legal office, after reasonable notice to the business, that the business is not taking appropriate measures to obtain a speedy resolution of the action. If the information has been found to be temporarily entitled to confidential treatment, the notice shall further state that the information will not be disclosed prior to the end of the period of such temporary entitlement to confidential treatment.

(3) The period established in a notice under paragraph (f)(2) of this section for commencement of an action to obtain judicial review may be extended if, before the expiration of such period, a request for an extension is made by the business and approved by the EPA legal office, or by any office acting pursuant to § 2.204(d)(2). Except in extraordinary circumstances, the EPA office will not approve such an extension without the consent of any person whose request for release of the information under 5 U.S.C. 552 is pending.

(4) After the expiration of any period of temporary entitlement to confidential treatment, a determination under this paragraph (f) of this section shall be implemented by the EPA legal office, or by any office acting pursuant to § 2.204(d)(2) (after consultation with the appropriate legal office) by making the information available to the public (in the absence of a court order prohibiting disclosure) whenever—

(i) The period provided for commencement by a business of an action to obtain judicial review of the determination has expired without notice to the EPA legal office of commencement of such an action;

(ii) The court, in a timely-commenced action, has denied the business' motion for a preliminary injunction, or has otherwise upheld the EPA determination; or

(iii) The EPA legal office, after reasonable notice has been provided to the business, finds that the business is not taking appropriate measures to obtain a speedy resolution of the timely-commenced action.

(5) Any person whose request for release of the information under 5 U.S.C. 552 is pending at the time notice is given under paragraph (f)(2) of this section shall be furnished a determination under 5 U.S.C. 552 stating the circumstances under which the information will be released.

(g) *Emergency situations.* If the General Counsel finds that disclosure of information covered by a claim would be helpful in alleviating a situation posing an imminent and substantial danger to public health or safety, he may prescribe and make known to interested persons such shorter comment period (paragraph (b) of this section), post-determination waiting period (paragraph (f) of this section), or both, as he finds necessary under the circumstances.

(h) *Modification of prior determinations.* A determination that information is entitled to confidential treatment for the benefit of a business, made under this subpart by an EPA legal office, shall continue in effect in accordance with its terms until an EPA legal office taking action under this section, or under § 2.206 or § 2.207, issues a final determination stating that the earlier determination no longer describes correctly the information's entitlement to confidential treatment because of a change in the applicable law, newly-discovered or changed facts, or because the earlier determination was clearly erroneous. If an EPA legal office tentatively concludes that such an earlier determination is of questionable validity, it shall so inform the business, and shall afford the business an opportunity to furnish comments on pertinent issues in the manner described by § 2.204(e) and paragraph (b) of this section. If, after consideration of any timely comments submitted by the business, the EPA legal office makes a revised final determination that the information is not entitled to confidential treatment, or that the period of entitlement to such treatment will end sooner than it would have ended under the earlier determination, the office will follow the procedure described in paragraph (f) of this section. Determinations under this section may be made only by, or with the concurrence of, the General Counsel.

(i) *Delegation and redelegation of authority.* Unless the General Counsel otherwise directs, or this subpart specifically provides, determinations

and actions required by this subpart to be made or taken by an EPA legal office shall be made or taken by the appropriate Regional Counsel whenever the EPA office taking action under § 2.204 or § 2.206(b) is under the supervision of a Regional Administrator, and by the General Counsel in all other cases. The General Counsel may redelegate any or all of his authority under this subpart to any attorney employed by EPA under the General Counsel's supervision. A Regional Counsel may redelegate any or all of his authority under this subpart to any attorney employed by EPA under the Regional Counsel's supervision.

§ 2.206 Advance confidentiality determinations.

(a) An advance determination under this section may be issued by an EPA legal office if—

(1) EPA has requested that a business furnish business information to EPA;

(2) The business asserts that the information, if submitted, would constitute voluntarily submitted information;

(3) The business will voluntarily submit the information for use by EPA only if EPA first determines that the information is entitled to confidential treatment under this subpart; and

(4) The EPA office which desires submission of the information has requested that the EPA legal office issue a determination under this section.

(b) The EPA office requesting an advance determination under this section shall—

(1) Arrange to have the business furnish directly to the EPA legal office a copy of the information (or, where feasible, a description of the nature of the information sufficient to allow a determination to be made), as well as the business' comments concerning the matters addressed in § 2.204(e)(3), excluding, however, matters addressed in § 2.204 (e)(3)(iii) and (e)(3)(iv); and

(2) Furnish to the EPA legal office the materials referred to in § 2.204(f) (3), (7), (8), and (9).

(c) In making a determination under this section, the EPA legal office shall first determine whether the information would constitute voluntarily submitted information. If the information would constitute voluntarily submitted information, the legal office shall further determine whether the information is entitled to confidential treatment.

(d) If the EPA legal office determines that the information would not constitute voluntarily submitted information, or determines that it would constitute voluntarily submitted information but would not be entitled to confidential treatment, it shall so inform the business and the EPA office which requested the determination, stating the basis of the determination, and shall return to the business all copies of the information which it may have received from the business (except that if a request under 5 U.S.C. 552 for release of the information is received while the EPA legal office is in possession of the information, the legal office shall retain a copy of the information, but shall not disclose it unless ordered by a Federal court to do so). The legal office shall not disclose the information to any other EPA office or employee and shall not use the information for any purpose except the determination under this section, unless otherwise directed by a Federal court.

(e) If the EPA legal office determines that the information would constitute voluntarily submitted information and that it is entitled to confidential treatment, it shall so inform the EPA office which requested the determination and the business which submitted it, and shall forward the information to the EPA office which requested the determination.

§ 2.207 Class determinations.

(a) The General Counsel may make and issue a class determination under this section if he finds that—

(1) EPA possesses, or is obtaining, related items of business information;

(2) One or more characteristics common to all such items of information will necessarily result in identical treatment for each such item under one or more of the provisions in this subpart, and that it is therefore proper to treat all such items as a class for one or more purposes under this subpart; and

(3) A class determination would serve a useful purpose.

(b) A class determination shall clearly identify the class of information to which it pertains.

(c) A class determination may state that all of the information in the class—

(1) Is, or is not, voluntarily submitted information;

(2) Is, or is not, governed by a particular section of this subpart, or by a particular set of substantive criteria under this subpart;

(3) Fails to satisfy one or more of the applicable substantive criteria, and is therefore ineligible for confidential treatment;

(4) Satisfies one or more of the applicable substantive criteria; or

(5) Satisfies one or more of the applicable substantive criteria during a certain period, but will be ineligible for confidential treatment thereafter.

(d) The purpose of a class determination is simply to make known the Agency's position regarding the manner in which information within the class will be treated under one or more of the provisions of this subpart. Accordingly, a class determination issued on or after [insert effective date of final rule] must be published in the **Federal Register** before it may be applied. The notice of opportunity to submit comments referred to in § 2.204(d)(1)(ii) and § 2.205(b), and the list of materials required to be furnished to the EPA legal office under § 2.204(d)(1)(iii), may be modified to reflect the fact that the class determination has made unnecessary the submission of materials pertinent to one or more issues. Moreover, in appropriate cases, action based on the class determination may be taken under § 2.204(b)(1), § 2.204(d), § 2.205(d), or § 2.206. However, the existence of a class determination shall not, of itself, affect any right a business may have to receive any notice under § 2.204(d)(2) or § 2.205(f).

§ 2.208 Substantive criteria for use in confidentiality determinations.

Determinations issued under §§ 2.204 through 2.207 shall hold that business information is entitled to confidential treatment for the benefit of a particular business if—

(a) The business has asserted a business confidentiality claim which has not expired by its terms, nor been waived nor withdrawn;

(b) The business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information, and that it intends to continue to take such measures;

(c) The information is not, and has not been, reasonably obtainable without the business' consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding);

(d) No statute specifically requires disclosure of the information; and

(e) Either—

(1) The information has been voluntarily submitted and the business has shown that it is of a kind that would not customarily be released to the public by the party from whom it was obtained; or

(2) The information has not been voluntarily submitted and either—

(i) The business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business' competitive position; or

(ii) Disclosure of the information would be likely to impair the Government's ability to obtain necessary information in the future.

§ 2.209 Disclosure in special circumstances.

(a) *General.* Information which, under this subpart, is not available to the public may nonetheless be disclosed to the persons, and in the circumstances, described by paragraphs (b) through (g) of this section. (This section shall not be construed to restrict the disclosure of information which has been determined to be available to the public. However, business information for which a claim of confidentiality has been asserted shall be treated as being entitled to confidential treatment until there has been a determination in accordance with the procedures of this subpart that the information is not entitled to confidential treatment.)

(b) *Disclosure to Congress or the Comptroller General.* (1) Upon receipt of a written request by the Speaker of the House, President of the Senate, chairman of a committee or subcommittee, or the Comptroller General, as appropriate, EPA will disclose business information to either House of Congress, to a committee or subcommittee of Congress, or to the Comptroller General, unless a statute forbids such disclosure.

(2) If the request is for business information claimed as confidential or determined to be confidential, the EPA office processing the request shall provide notice to each affected business of the type of information disclosed and to whom it is disclosed. Notice shall be given at least ten days prior to disclosure, except where it is not possible to provide notice ten days in advance of any date established by the requesting body for responding to the request. Where ten days advance notice cannot be given, as much advance notice as possible shall be provided. Where notice cannot be given before the date established by the requesting body for responding to the request, notice shall be given as promptly after disclosure as possible. Such notice may be given by notice published in the **Federal Register** or by letter sent by certified mail, return receipt requested, or telegram. However, if the requesting body asks in writing that no notice under this subsection be given, EPA will give no notice.

(3) At the time EPA discloses the business information, EPA will inform the requesting body of any unresolved business confidentiality claim known to cover the information and of any determination under this subpart that the information is entitled to confidential treatment.

(c) *Disclosure to other Federal agencies.* EPA may disclose business information to another Federal agency if—

(1) EPA receives a written request for disclosures of the information from a duly authorized officer or employee of the other agency or on the initiative of EPA when such disclosure is necessary to enable the other agency to carry out a function on behalf of EPA;

(2) The request, if any, sets forth the official purpose for which the information is needed;

(3) When the information has been claimed as confidential or has been determined to be confidential, the responsible EPA office provides notice to each affected business of the type of information to be disclosed and to whom it is to be disclosed. At the discretion of the office, such notice may be given by notice published in the **Federal Register** at least 10 days prior to disclosure, or by letter sent by certified mail return receipt requested or telegram, either of which must be received by the affected business at least 10 days prior to disclosure. However, no notice shall be required when EPA furnishes business information to another Federal agency—

(i) To perform a function on behalf of EPA, including but not limited to—

(A) Disclosure to the Department of Justice for purposes of investigation or prosecution of civil or criminal violations of Federal law related to EPA activities;

(B) Disclosure to the Department of Justice for purposes of representing EPA in any matter; and

(C) Disclosure to any Federal agency for purposes of performing an EPA statutory function under an interagency agreement; or

(ii) In connection with a law enforcement investigation by the other Federal agency;

(4) EPA notifies the other agency of any unresolved business confidentiality claim covering the information and of any determination under this subpart that the information is entitled to confidential treatment, and that further disclosure of the information may be a violation of 18 U.S.C. 1905; and

(5) The other agency agrees in writing not to disclose further any information designated as confidential unless—

(i) The other agency has statutory authority both to compel production of the information and to make the proposed disclosure, and the other agency has, prior to disclosure of the information to anyone other than its officers and employees, furnished to each affected business at least the same notice to which the affected business would be entitled under this subpart;

(ii) The other agency has obtained the consent of each affected business to the proposed disclosure; or

(iii) The other agency has obtained a written statement from the EPA General Counsel or an EPA Regional Counsel that disclosure of the information would be proper under this subpart.

(d) *Court-ordered disclosure.* EPA may disclose any business information in any manner and to the extent ordered by a Federal court. Where possible, and when not in violation of a specific directive from the court, the EPA office disclosing information claimed as confidential or determined to be confidential shall provide as much advance notice as possible to each affected business of the type of information to be disclosed and to whom it is to be disclosed, unless the affected business has actual notice of the court order. At the discretion of the office, subject to any restrictions by the court, such notice may be given by notice in the **Federal Register**, letter sent by certified mail return receipt requested, or telegram.

(e) *Disclosure within EPA.* An EPA office, officer, or employee may disclose any business information to another EPA office, officer, or employee with an official need for the information.

(f) *Disclosure with consent of business.* EPA may disclose any business information to any person if EPA has obtained the prior consent of each affected business to such disclosure.

(g) *Disclosures to foreign governments and international organizations.* (1) EPA may disclose business information to a foreign government or to an international organization if—

(i) Either—

(A) EPA receives a written request for disclosure of the information from a duly authorized officer or employee of the foreign government or international organization (or from a duly authorized officer or employee of another agency of the United States Government); or

(B) The EPA office making such disclosure determines in writing that disclosure is necessary to enable the foreign government or international organization to assist EPA in carrying out a function of EPA, or to enable EPA to assist the foreign government or international organization with a duly-authorized function of that foreign government or international organization;

(ii) The request, if any, sets forth the official purpose for which the information is needed;

(iii) The General Counsel, after consideration of applicable statutes, treaties, and other international agreements, has determined that EPA has authority to make such disclosure;

(iv) At least 10 days prior to disclosure, the responsible EPA office provides notice to each affected business by **Federal Register**, certified mail, return receipt requested, or other appropriate means of the type of information to be disclosed and to whom it is to be disclosed, and an opportunity to comment on the intended disclosure (except where the Director of the Office of Criminal Enforcement has determined that providing such notice would interfere with an ongoing or contemplated criminal investigation, or the Director of the Office of Regulatory Enforcement or a Regional Counsel has determined that providing such notice might compromise an ongoing or contemplated civil law enforcement investigation);

(v) EPA notifies the foreign government or international organization of any unresolved business confidentiality claim covering the information and of any determination under this subpart that the information is entitled to confidential treatment; and

(vi) The General Counsel has determined that the foreign government's or international organization's use and disclosure of such information will be governed by law and procedures or other binding commitments which will provide adequate protection to the interests of affected businesses.

(2) The General Counsel may waive any requirement in this paragraph (g) if the General Counsel determines that a statute, treaty, or other international agreement prohibits EPA from implementing the requirement.

(3) For purposes of this paragraph (g), the term *foreign government* means any foreign government or any department, agency, or other unit of a foreign government, and the term *international organization* means any public international organization, subdivision of a public international organization or public international organization preparatory commission, whether or not the United States is a member of the public international organization, the subdivision, or the preparatory commission in question.

§ 2.210 Nondisclosure for reasons other than business confidentiality or where disclosure is prohibited by other statute.

(a) Information which is not entitled to confidential treatment under this subpart shall be made available to the public (using the procedures set forth in §§ 2.204 and 2.205) if its release is requested under 5 U.S.C. 552, unless EPA determines (under subpart A of this part) that, for reasons other than reasons of business confidentiality, the information is exempt from mandatory disclosure and cannot or should not be made available to the public. Any such determination under subpart A shall be coordinated with actions taken under this subpart for the purpose of avoiding delay in responding to requests under 5 U.S.C. 552.

(b) Notwithstanding any other provision of this subpart, if any statute not cited in this subpart appears to require EPA to give confidential treatment to any business information for reasons of business confidentiality, the matter shall be referred promptly to an EPA legal office for resolution. Pending resolution, such information shall be treated as if it were entitled to confidential treatment.

§ 2.211 Safeguarding of business information; penalty for wrongful disclosure.

(a) No EPA officer or employee may disclose, or use for his or her private gain or advantage, any business information which came into his or her possession, or to which he or she gained access, by virtue of his or her official position or employment, except as authorized by this subpart.

(b) Each EPA officer or employee who has custody or possession of business information shall take appropriate measures to properly safeguard such information and to protect against its improper disclosure.

(c) Violation of paragraph (a) or (b) of this section shall constitute grounds for dismissal, suspension, or other adverse personnel action. Willful violation of paragraph (a) of this section may result in criminal prosecution under 18 U.S.C. 1905 or other applicable statute.

(d) Each contractor or subcontractor with the United States Government, and each employee of such contractor or subcontractor, who is furnished business information by EPA under §§ 2.301(h), 2.302(h), 2.304(h), 2.305(h), 2.306(j), 2.307(h), 2.308(i), or § 2.310(h) shall use or disclose that information only as permitted by the contract or subcontract under which the information was furnished. Contractors or subcontractors shall take steps to properly safeguard business information including following any security procedures for handling and safeguarding business information which are contained in any manuals, procedures, regulations, or guidelines provided by EPA. Any violation of this paragraph shall constitute grounds for suspension or debarment of the contractor or subcontractor in question. A willful violation of this paragraph may result in criminal prosecution under an applicable statute.

(e) Each grantee or cooperator under the Senior Environmental Employment Program (pursuant to the Environmental Programs Assistance Act of 1984 (Pub.L. 98–313)), and each enrollee associated with a grantee or cooperator, who is furnished business information by EPA under §§ 2.301(h), 2.302(h), 2.304(h), 2.305(h), 2.307(h), 2.308(i), or § 2.310(h) shall use or disclose that information only as permitted by the grant or cooperative agreement under which the information was furnished. Grantees, cooperators, and enrollees shall take steps to properly safeguard business information including following any security procedures for handling and safeguarding business information which are contained in any manuals, procedures, regulations, or guidelines provided by EPA. If an enrollee under the program violates this paragraph, EPA may terminate the enrollee's eligibility for the program. A willful violation of this paragraph may result in criminal prosecution under an applicable statute.

§ 2.212 Establishment of control offices for categories of business information.

(a) The Administrator, by order, may establish one or more mutually exclusive categories of business information, and may designate for each such category an EPA office (hereinafter referred to as a control office) which shall have responsibility for taking actions (other than actions required to be taken by an EPA legal office) with respect to all information within such category.

(b) If a control office has been assigned responsibility for a category of business information, no other EPA office, officer, or employee may make available to the public (or otherwise disclose to persons other than EPA officers and employees) any information in that category without first obtaining the concurrence of the control office. Requests under 5 U.S.C. 552 for release of such information shall be referred to the control office.

(c) A control office shall take the actions and make the determinations required by § 2.204 with respect to all information in any category for which the control office has been assigned responsibility.

(d) A control office shall maintain a record of the following, with respect to items of business information in

categories for which it has been assigned responsibility:

(1) Business confidentiality claims;

(2) Comments submitted in support of claims;

(3) Waivers and withdrawals of claims;

(4) Actions and determinations by EPA under this subpart;

(5) Actions by Federal courts; and

(6) Related information concerning business confidentiality.

§ 2.213 Designation by business of addressee for notices and inquiries.

(a) A business which wishes to designate a person or office as the proper addressee of communications from EPA to the business under this subpart may do so by furnishing in writing to the Freedom of Information Officer (1105), Environmental Protection Agency, 401 M St. SW., Washington, DC 20460, the following information: The name and address of the business making the designation; the name, address, and telephone number of the designated person or office; and a request that EPA inquiries and communications (oral and written) under this subpart, including inquiries and notices which require reply within deadlines if the business is to avoid waiver of its rights under this subpart, be furnished to the designee pursuant to this section. Only one person or office may serve at any one time as a business' designee under this subpart.

(b) If a business has named a designee under this section, the following EPA inquiries and notices to the business shall be addressed to the designee:

(1) Inquiries concerning a business' desire to assert a business confidentiality claim under § 2.204(c)(2)(i)(A);

(2) Notices affording opportunity to substantiate confidentiality claims under § 2.204(d)(1) and § 2.204(e);

(3) Inquires concerning comments under § 2.205(b)(4);

(4) Notices of denial of confidential treatment and proposed disclosure of information under § 2.205(f);

(5) Notices concerning shortened comment and/or waiting periods under § 2.205(g);

(6) Notices concerning modifications or overrulings of prior determinations under § 2.205(h);

(7) Notices to affected businesses under §§ 2.301(g) and 2.301(h) and analogous provisions in §§ 2.302, 2.303, 2.304, 2.305, 2.306, 2.307, 2.308 and 2.310; and

(8) Notices to affected businesses under § 2.209.

(c) The Freedom of Information Officer shall, as quickly as possible, notify all EPA offices that may possess information submitted by the business to EPA, the Regional Freedom of Information Offices, the Office of General Counsel, and the offices of Regional Counsel of any designation received under this section. Businesses making designations under this section should mind that several working days may be required for dissemination of this information within EPA and that some EPA offices may not receive notice of such designations.

§ 2.214 Defense of Freedom of Information Act suits; participation by affected business.

(a) In making final confidentiality determinations under this subpart, the EPA legal office relies to a large extent upon the information furnished by the affected business to substantiate its claim of confidentiality. The EPA legal office may be unable to verify the accuracy of much of the information submitted by the affected business.

(b) If the EPA legal office makes a final confidentiality determination under this subpart that certain business information is entitled to confidential treatment, and EPA is sued by a requester under the Freedom of Information Act for disclosure of that information, EPA will:

(1) Notify each affected business of the suit within 10 days after service of the complaint upon EPA;

(2) Where necessary to preparation of EPA's defense, call upon each affected business to furnish assistance; and

(3) Not oppose a motion by any affected business to intervene as a party to the suit under rule 24(b) of the Federal Rules of Civil Procedure.

(c) EPA will defend its final confidentiality determination, but EPA expects the affected business to cooperate to the fullest extent possible in this defense.

§ 2.215 Confidentiality agreements.

(a) No EPA officer, employee, contractor, or subcontractor shall enter into any agreement with any affected business to keep business information confidential unless such agreement is consistent with this subpart. No EPA officer, employee, contractor, or subcontractor shall promise any affected business that business information will be kept confidential unless the promise is consistent with this subpart.

(b) If an EPA office has requested information from a State, local, or Federal agency and the agency refuses to furnish the information to EPA because the information is or may constitute confidential business information, the EPA office may enter into an agreement with the agency to keep the information confidential, notwithstanding the provisions of this subpart. However, no such agreement shall be made unless the General Counsel determines that the agreement is necessary and proper.

(c) To determine that an agreement proposed under paragraph (b) of this section is necessary, the General Counsel must find:

(1) The EPA office requesting the information needs the information to perform its functions;

(2) The agency will not furnish the information to EPA without an agreement by EPA to keep the information confidential; and

(3) Either:

(i) EPA has no statutory power to compel submission of the information directly from the affected business, or

(ii) While EPA has statutory power to compel submission of the information directly from the affected business, compelling submission of the information directly from the business would—

(A) Require time in excess of that available to the EPA office to perform its necessary work with the information,

(B) Duplicate information already collected by the other agency and overly burden the affected business, or

(C) Overly burden the resources of EPA.

(d) To determine that an agreement proposed under paragraph (b) of this section is proper, the General Counsel must find that the agreement states—

(1) The purpose for which the information is required by EPA;

(2) The conditions under which the agency will furnish the information to EPA;

(3) The information subject to the agreement;

(4) That the agreement does not cover information acquired by EPA from another source;

(5) The manner in which EPA will treat the information; and

(6) That EPA will treat the information in accordance with the agreement subject to an order of a Federal court to disclose the information.

(e) EPA will treat any information acquired pursuant to an agreement under paragraph (b) of this section in accordance with the procedures of this subpart except where the agreement specifies otherwise.

§ 2.216 Sunset Provisions for Confidentiality Claims.

(a) Any claim of confidentiality asserted under this subpart will expire if—

(1) The claim is subject to a regulation meeting the requirements of paragraph (b) of this section;

(2) No affected business has met the requirements of paragraphs (c) and (d) of this section during the period of time specified in paragraph (c) of this section; and

(3) The sunset period or event set by the regulation referred to in paragraph (a)(1) of this section has passed or occurred.

(b) Any regulation which causes a confidentiality claim to expire must specify—

(1) The class of information subject to the sunset provision; and

(2) The period of time which must pass or the event which must occur to cause the confidentiality claim to expire.

(c) A claim of confidentiality subject to a regulation meeting the requirements of paragraph (b) of this section will not expire if an affected business reasserts the confidentiality claim within 90 calendar days prior to the expiration of the period, or within 90 days subsequent to the occurrence of the event, set forth in paragraph (b) of this section. A regulation under paragraph (b) of this section may provide for a reassertion period of less than 90 days.

(d) An officer of the affected business must sign the reassertion of confidentiality submitted pursuant to paragraph (c) of this section and must certify to the truth of the following statements concerning the information reasserted to be confidential:

(1) My company has continually taken measures to protect the confidentiality of the information, and intends to continue to take such measures.

(2) The information is not, and has not been, reasonably obtainable without our consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding).

(3) The information is not publicly available elsewhere.

(4) If the information was not submitted voluntarily to EPA, disclosure of the information would cause substantial harm to our competitive position.

(e) A confidentiality claim which has expired pursuant to paragraph (a) of this section is deemed waived, and the information subject to that claim may be disclosed to the public without further notice to the affected business.

§ 2.217–2.300 [Reserved]

§ 2.301 Special rules governing certain information obtained under the Clean Air Act.

(a) *Definitions.* For the purpose of this section:

(1) *Act* means the Clean Air Act, as amended, 42 U.S.C. 7401 et seq.

(2)(i) *Emission data* means, with reference to any source of emission of any substance into the air—

(A) Information necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of any emission which has been emitted by the source (or of any pollutant resulting from any emission by the source), or any combination of the foregoing;

(B) Information necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of the emissions which, under an applicable standard or limitation, the source was authorized to emit (including, to the extent necessary for such purposes, a description of the manner or rate of operation of the source); and

(C) A general description of the location and/or nature of the source to the extent necessary to identify the source and to distinguish it from other sources (including, to the extent necessary for such purposes, a description of the device, installation, or operation constituting the source).

(ii) Notwithstanding paragraph (a)(2)(i) of this section, the following information shall be considered to be emission data only to the extent necessary to allow EPA to disclose publicly that a source is (or is not) in compliance with an applicable standard or limitation, or to allow EPA to demonstrate the feasibility, practicability, or attainability (or lack thereof) of an existing or proposed standard or limitation:

(A) Information concerning research, or the results of research, on any project, method, device or installation (or any component thereof) which was produced, developed, installed, and used only for research purposes; and

(B) Information concerning any product, method, device, or installation (or any component thereof) designed and intended to be marketed or used commercially but not yet so marketed or used.

(3) *Standard or limitation* means any emission standard or limitation (including a standard or limitation that must be disclosed under subchapter VI of the Act in connection with allocation of production and consumption allowances for ozone depleting substances) established or publicly proposed pursuant to the Act or pursuant to any regulation under the Act.

(4) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this subpart.

(5) *Manufacturer* has the meaning given it in section 216(1) of the Act, 42 U.S.C. 7550(1).

(b) *Applicability. (1) This section applies to business information which was—*

(i) Provided or obtained under section 114 of the Act, 42 U.S.C. 7414, by the owner or operator of any stationary source, for the purpose:

(A) of developing or assisting in the development of any implementation plan under section 110 or 111(d) of the Act, 42 U.S.C. 7410, 7411(d), any standard of performance under section 111 of the Act, 42 U.S.C. 7411, or any emission standard under section 112 of the Act, 42 U.S.C. 7412;

(B) of determining whether any person is in violation of any such standard or any requirement of such a plan; or

(C) of carrying out any provision of the Act (except a provision of Part II of the Act with respect to a manufacturer of new motor vehicles or new motor vehicle engines);

(ii) Provided or obtained under section 208 of the Act, 42 U.S.C. 7542, for the purpose of enabling the Administrator to determine whether a manufacturer has acted or is acting in compliance with part A and part C of Subchapter II of the Act and regulations thereunder, or to otherwise carry out the provisions of part A and part C of Subchapter II of the Act, or provided or obtained under section 206(c) of the Act, 42 U.S.C. 7525(c); or

(iii) Provided in response to a subpoena for the production of papers, books, or documents issued under the authority of section 307(a) of the Act, 42 U.S.C. 7607(a).

(2) Information will be considered to have been provided or obtained under section 114 of the Act if it was provided in response to a request by EPA made for any of the purposes stated in section 114, or if its submission could have been required under section 114, regardless of whether section 114 was cited as the authority for any request for the information, whether an order to provide the information was issued under section 113(a) of the Act, 42 U.S.C. 7413(a), whether an action was brought under section 113(b) of the Act,

42 U.S.C. 7413(b), or whether the information was provided directly to EPA or through some third person.

(3) Information will be considered to have been provided or obtained under section 208 of the Act if it was provided in response to a request by EPA made for any of the purposes stated in section 208, or if its submission could have been required under section 208, regardless of whether section 208 was cited as the authority for any request for the information, whether an action was brought under section 204 of the Act, 42 U.S.C. 7523, or whether the information was provided directly to EPA or through some third person.

(4) Information will be considered to have been provided or obtained under section 206(c) of the Act if it was provided in response to a request by EPA made for any of the purposes stated in section 206(c), or if its submission could have been required under section 206(c) regardless of whether section 206(c) was cited as authority for any request for the information, whether an action was brought under section 204 of the Act, 42 U.S.C. 7523, or whether the information was provided directly to EPA or through some third person.

(5) Information will be considered to have been provided or obtained under section 307(a) of the Act if it was provided in response to a subpoena issued under section 307(a), or if its production could have been required by subpoena under section 307(a), regardless of whether section 307(a) was cited as the authority for any request for the information, whether a subpoena was issued by EPA, whether a court issued an order under section 307(a), or whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201, 2.202, 2.204 through 2.207, § 2.209 and § § 2.211 through 2.216 apply without change to information to which this section applies.

(d) Section 2.203 applies to information to which this section applies, except that:

(1) Information submitted pursuant to 40 CFR part 57, Primary Nonferrous Smelter Orders, shall be subject to the requirements of § 57.203(a) and Appendix A of this chapter, instruction 1.3;

(2) Information submitted pursuant to 40 CFR part 85, Control of Air Pollution from Motor Vehicles and Motor Vehicle Engines, shall be subject to the requirements of §§ 85.1514, 85.1712, 85.1808, 85.1909, 85.2123 and 85.408 of this chapter; and

(3) Information submitted pursuant to 40 CFR part 86, Control of Air Pollution from New and In-Use Motor Vehicles and New and In-Use Motor Vehicle Engines: Certification and Test Procedures, shall be subject to the requirements of §§ 86.1015, 86.1116–87 and 86.615–84 of this chapter.

(e) *Substantive criteria for use in confidentiality determinations.* (1) Section 2.208 applies to information to which this section applies, except that information which is emission data, a standard or limitation (including a standard or limitation that must be disclosed under subchapter VI of the Act in connection with allocation of production and consumption allowances for ozone depleting substances), or is collected pursuant to section 211(b)(2)(A) of the Act is not eligible for confidential treatment.

(2) The following information, when submitted pursuant to a request for information under section 114 of the Act, constitutes emission data (but is not an exhaustive list of information which is emission data) and, notwithstanding any claims of confidentiality, may be disclosed to the public without notice to affected businesses:

(i) Plant name and related point identifiers, including address, city, county, Air Quality Control Region (AQCR), Metropolitan Statistical Area (MSA, PMSA, CMSA), State, zip code;

(ii) Ownership and point of contact information locational identifiers, including latitude and longitude, or Universal Transverse Mercator (UTM) grid coordinates, standard industrial classification (SIC), emission point, device or operation description information, and source classification codes (SCC); and

(iii) Emissions parameters, including emission type, emission rate, release height, description of terrain and surrounding structures, stack or vent diameter at point of emissions, release velocity, release temperature, frequency of release, duration of release, concentration, density of emissions stream or average molecular weight, boiler or process design capacity, emission estimation method, percent space heat, and hourly maximum design rate.

(f) *Availability of information not entitled to confidential treatment.* Section 2.210 does not apply to information to which this section applies. Emission data, standards or limitations, and any other information provided under section 114 or 208 of the Act which is determined under this subpart not to be entitled to confidential treatment, shall be available to the public notwithstanding any other provision of this part. Emission data and standards or limitations provided in response to a subpoena issued under section 307(a) of the Act shall be available to the public notwithstanding any other provision of this part. Information (other than emission data and standards or limitations) provided in response to a subpoena issued under section 307(a) of the Act, which is determined under this subpart not to be entitled to confidential treatment, shall be available to the public, unless EPA determines that the information is exempt from mandatory disclosure under 5 U.S.C. 552(b) for reasons other than reasons of business confidentiality and cannot or should not be made available to the public.

(g) *Disclosure of information relevant to a proceeding.* (1) Under sections 114, 208 and 307 of the Act, any information to which this section applies may be released by EPA because of the relevance of the information to a proceeding, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2) In connection with any proceeding other than a proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, information to which this section applies which may be entitled to confidential treatment may be made available to the public under this paragraph (g)(2). No information shall be made available to the public under this paragraph (g)(2) until any affected business has been informed that EPA is considering making the information available to the public under this paragraph (g)(2) in connection with an identified proceeding, and has afforded the business a reasonable period for comment (such notice and opportunity to comment may be afforded in connection with the notice prescribed by §§ 2.204(d)(1) and 2.204(e)). Information may be made available to the public under this paragraph (g)(2) only if, after consideration of any timely comments submitted by the business, the General Counsel determines that the information is relevant to the subject of the proceeding and the EPA office conducting the proceeding determines that the public interest would be served by making the information available to the public. Any affected business shall be given at least 5 days notice by the General Counsel prior to making the information available to the public.

(3) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, information to which this section applies which may be entitled to confidential treatment may be made available to the public, or to one or more parties of record to the proceeding, upon EPA's initiative, under this paragraph (g)(3). An EPA office proposing disclosure of information under this paragraph (g)(3), shall so notify the presiding officer in writing. Upon receipt of such a notification, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(3) has been proposed, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed under this paragraph (g)(3) only if, after consideration of any timely comments submitted by the business, the EPA office determines in writing that, for reasons directly associated with the conduct of the proceeding, the contemplated disclosure would serve the public interest, and the presiding officer determines in writing that the information is relevant to a matter in controversy in the proceeding. The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as the presiding officer finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information for confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to the public or to one or more of the parties of record to the proceeding.

(4) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, information to which this section applies may be made available to one or more parties of record to the proceeding, upon request of a party, under this paragraph (g)(4). A party of record seeking disclosure of information shall direct its request to the presiding officer. Upon receipt of such a request, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(4) has been requested, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed to a party of record under this paragraph (g)(4) only if, after consideration of any timely comments submitted by the business, the presiding officer determines in writing that: the party of record has satisfactorily shown that with respect to a significant matter which is in controversy in the proceeding, the party's ability to participate effectively in the proceeding will be significantly impaired unless the information is disclosed to him; and any harm to an affected business that would result from the disclosure is likely to be outweighed by the benefit to the proceeding and to the public interest that would result from the disclosure. The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information to confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to one or more of the parties of record to the proceeding.

(h) *Disclosure to authorized representatives.* (1) Under sections 114, 208 and 307(a) of the Act, EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h) (2) or (3) of this section.

(2)(i) A person under contract or subcontract to the United States Government to perform work in support of EPA in connection with the Act or regulations which implement the Act may be considered an authorized representative of the United States for purposes of this paragraph (h). For purposes of this section, the term "contract" includes grants and cooperative agreements under the Environmental Programs Assistance Act of 1984 (Pub. L. 98–313), and the term "contractor" includes grantees and cooperators under the Environmental Programs Assistance Act of 1984. Subject to the limitations in this paragraph (h)(2), information to which this section applies may be disclosed—

(A) To a contractor or subcontractor with EPA, if the EPA program office managing the contract first determines in writing that such disclosure is necessary in order that the contractor or subcontractor may carry out the work required by the contract or subcontract; or

(B) To a contractor or subcontractor with an agency other than EPA, if the EPA program office which provides the information to that agency, contractor, or subcontractor first determines in writing, in consultation with the General Counsel, that such disclosure is necessary in order that the contractor or subcontractor may carry out the work required by the contract or subcontract.

(ii) No information shall be disclosed under this paragraph (h)(2), unless this contract or subcontract in question provides:

(A) That the contractor or subcontractor and the contractor's or subcontractor's employees shall use the information only for the purpose of carrying out the work required by the contract or subcontract, shall refrain from disclosing the information to anyone other than EPA without the prior written approval of each affected business or of an EPA legal office, and shall return to EPA all copies of the information (and any abstracts or extracts therefrom) upon request by the EPA program office whenever the information is no longer required by the contractor or subcontractor for the performance of the work required under the contract or subcontract or upon completion of the contract or subcontract (where the information was provided to the contractor or subcontractor by an agency other than EPA, the contractor may disclose or return the information to that agency);

(B) That the contractor or subcontractor shall obtain a written agreement to honor such terms of the contract or subcontract from each of the contractor's or subcontractor's employees who will have access to the information, before such employee is allowed such access; and

(C) That the contractor or subcontractor acknowledges and agrees that the contract or subcontract provisions concerning the use and disclosure of business information are included for the benefit of, and shall be enforceable by, both the United States Government and any affected business having an interest in information concerning it supplied to the contractor or subcontractor by the United States Government under the contract or subcontract.

(iii) No information shall be disclosed under this paragraph (h)(2) until each affected business has been furnished notice (by letter, **Federal Register**, or other means) of the contemplated disclosure by the EPA program and has

been afforded a period found reasonable by that office (not less than 5 working days) to submit its comments. Such notice shall include a description of the information to be disclosed, the identity of the contractor or subcontractor, and the purposes to be served by the disclosure. The office preparing the notice must respond in writing to all comments.

(3) A State or local governmental agency which has duties or responsibilities under the Act, or under regulations which implement the Act, may be considered an authorized representative of the United States for purposes of this paragraph (h). Information to which this section applies may be furnished to such an agency at the agency's written request, but only if—

(i) The agency has first furnished to the EPA office having custody of the information a written opinion from the agency's chief legal officer or counsel stating that under applicable State or local law the agency has the authority to compel a business which possesses such information to disclose it to the agency; or

(ii) Each affected business is informed (by letter, **Federal Register**, or other means) of those disclosures under this paragraph (h)(3) which pertain to it, and the agency has shown to the satisfaction of an EPA legal office that the agency's use and disclosure of such information will be governed by State or local law and procedures which will provide adequate protection to the interests of affected businesses.

§ 2.302 Special rules governing certain information obtained under the Clean Water Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Clean Water Act, as amended, 33 U.S.C. 1251 et seq.

(2)(i) *Effluent data* means, with reference to any source of discharge of any pollutant (as that term is defined in section 502(6) of the Act, 33 U.S.C. 1362 (6))—

(A) Information necessary to determine the identity, amount, frequency, concentration, temperature, or other characteristics (to the extent related to water quality) of any pollutant which has been discharged by the source (or of any pollutant resulting from any discharge from the source), or any combination of the foregoing;

(B) Information necessary to determine the identity, amount, frequency, concentration, temperature, or other characteristics (to the extent related to water quality) of the pollutants which, under an applicable standard or limitation, the source was authorized to discharge (including, to the extent necessary for such purpose, a description of the manner or rate of operation of the source); and

(C) A general description of the location and/or nature of the source to the extent necessary to identify the source and to distinguish it from other sources (including, to the extent necessary for such purposes, a description of the device, installation, or operation constituting the source).

(ii) Notwithstanding paragraph (a)(2)(i) of this section, the following information shall be considered to be effluent data only to the extent necessary to allow EPA to disclose publicly that a source is (or is not) in compliance with an applicable standard or limitation, or to allow EPA to demonstrate the feasibility, practicability, or attainability (or lack thereof) of an existing or proposed standard or limitation:

(A) Information concerning research, or the results of research, on any product, method, device, or installation (or any component thereof) which was produced, developed, installed, and used only for research purposes; and

(B) Information concerning any product, method, device, or installation (or any component thereof) designed and intended to be marketed or used commercially but not yet so marketed or used.

(3) *Standard or limitation* means any prohibition, any effluent limitation, or any toxic, pre-treatment or new source performance standard established or publicly proposed pursuant to the Act or pursuant to regulations under the Act, including limitations or prohibitions in a permit issued or proposed by EPA or by a State under section 402 of the Act, 33 U.S.C. 1342.

(4) Proceeding means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this part.

(b) *Applicability.* (1) This section applies only to business information—

(i) Provided to or obtained by EPA under section 308 of the Act, 33 U.S.C. 1318, by or from the owner or operator of any point source, for the purpose of carrying out the objective of the Act (including but not limited to developing or assisting in the development of any standard or limitation under the Act, or in determining whether any person is in violation of any such standard or limitation); or

(ii) Provided to or obtained by EPA under section 509(a) of the Act, 33 U.S.C. 1369(a).

(2) Information will be considered to have been provided or obtained under section 308 of the Act if it was provided in response to a request by EPA made for any of the purposes stated in section 308, or if its submission could have been required under section 308, regardless of whether section 308 was cited as the authority for any request for the information, whether an order to provide the information was issued under section 309(a)(3) of the Act, 33 U.S.C. 1319(a)(3), whether a civil action was brought under section 309(b) of the Act, 33 U.S.C. 1319(b), and whether the information was provided directly to EPA or through some third person.

(3) Information will be considered to have been provided or obtained under section 509(a) of the Act if it was provided in response to a subpoena issued under section 509(a), or if its production could have been required by subpoena under section 509(a), regardless of whether section 509(a) was cited as the authority for any request for the information, whether a subpoena was issued by EPA, whether a court issued an order under section 307(a), or whether the information was provided directly to EPA or through some third person.

(4) This section specifically does not apply to information obtained under section 310(d) or 312(g)(3) of the Act, 33 U.S.C. 1320(d), 1322(g)(3).

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207, 2.209, 2.211 through 2.216 apply without change to information to which this section applies.

(d) [*Reserved*]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies to information to which this section applies, except that the following information is not eligible for confidential treatment:

(1) Information which is effluent data or a standard or limitation;

(2) Name and address of any permit applicant or permittee under part 122 of this chapter, part 501 of this chapter, or Section 404 of the Act; and

(3) Any permit application (including any attachments used to supply information required by the applications forms) or permit under part 122 of this chapter, part 501 of this chapter, or Section 404 of the Act.

(f) *Availability of information not entitled to confidential treatment.* Section 2.210 does not apply to information to which this section applies. Effluent data, standards or limitations, or any other information provided or obtained under section 308 of the Act which is determined under this subpart not to be entitled to

confidential treatment, shall be available to the public notwithstanding any other provision of this part. Effluent data and standards or limitations provided in response to a subpoena issued under section 509(a) of the Act shall be available to the public notwithstanding any other provision of this part. Information (other than effluent data and standards or limitations) provided in response to a subpoena issued under section 509(a) of the Act, which is determined under this subpart not to be entitled to confidential treatment, shall be available to the public, unless EPA determines that the information is exempt from mandatory disclosure under 5 U.S.C. 552(b) for reasons other than reasons of business confidentiality and cannot or should not be made available to the public.

(g) *Disclosure of information relevant to a proceeding.* (1) Under sections 308 and 509(a) of the Act, any information to which this section applies may be released by EPA because of the relevance of the information to a proceeding, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information to which this section applies because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2) The provisions of § 2.301(g) (2), (3), and (4) must be followed when making disclosures pursuant to this paragraph (g).

(h) *Disclosure to authorized representatives.* (1) Under sections 308 and 509(a) of the Act, EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2) The provisions of § 2.301(h) (2) and (3) must be followed when making disclosures pursuant to this paragraph (h).

§ 2.303 Special rules governing certain information obtained under the Noise Control Act of 1972.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Noise Control Act of 1972, 42 U.S.C. 4901 et seq.

(2) *Manufacturer* has the meaning given it in 42 U.S.C. 4902(6).

(3) *Product* has the meaning given it in 42 U.S.C. 4902(3).

(4) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this subpart.

(b) *Applicability.* This section applies only to information provided to or obtained by EPA under section 13 of the Act, 42 U.S.C. 4912, by or from any manufacturer of any product to which regulations under section 6 or 8 of the Act (42 U.S.C. 4905, 4907) apply. Information will be deemed to have been provided or obtained under section 13 of the Act, if it was provided in response to a request by EPA made for the purpose of enabling EPA to determine whether the manufacturer has acted or is acting in compliance with the Act, or if its submission could have been required under section 13 of the Act regardless of whether section 13 was cited as authority for the request, whether an order to provide such information was issued under section 11(d) of the Act, 42 U.S.C. 4910(d), and whether the information was provided directly to EPA by the manufacturer or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.216 apply without change to information to which this section applies.

(d) [*Reserved*]

(e) [*Reserved*]

(f) [*Reserved*]

(g) *Disclosure of information relevant to a proceeding.* (1) Under section 13 of the Act, any information to which this section applies may be released by EPA because of its relevance to a matter in controversy in a proceeding, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2) The provisions of § 2.301(g) (2), (3), and (4) must be followed when making disclosures pursuant to this paragraph (g).

§ 2.304 Special rules governing certain information obtained under the Safe Drinking Water Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Safe Drinking Water Act, 42 U.S.C. 300f et seq.

(2) *Contaminant* means any physical, chemical, biological, or radiological substance or matter in water.

(3) *Proceeding* means any rulemaking, adjudication, or licensing process conducted by EPA under the Act or under regulations which implement the Act, except for any determination under this part.

(b) *Applicability.* (1) This section applies only to information—

(i) Which was provided to or obtained by EPA pursuant to a requirement of a regulation which was issued by EPA under the Act for the purpose of—

(A) Assisting the Administrator in establishing regulations under the Act;

(B) Determining whether the person providing the information has acted or is acting in compliance with the Act; or

(C) Administering any program of financial assistance under the Act; and

(ii) Which was provided by a person—

(A) Who is a supplier of water, as defined in section 1401(5) of the Act, 42 U.S.C. 300f(5);

(B) Who is or may be subject to a primary drinking water regulation under section 1412 of the Act, 42 U.S.C. 300g–1;

(C) Who is or may be subject to an applicable underground injection control program, as defined in section 1422(d) of the Act, 42 U.S.C.300h–1(d);

(D) Who is or may be subject to the permit requirements of section 1424(b) of the Act, 42 U.S.C. 300h–3(b);

(E) Who is or may be subject to an order issued under section 1441(c) of the Act, 42 U.S.C. 300j(c); or

(F) Who is a grantee, as defined in section 1445(e) of the Act, 42 U.S.C. 300j–4(e).

(2) This section applies to any information which is described by paragraph (b)(1) of this section if it was provided in response to a request by EPA or its authorized representative (or by a State agency administering any program under the Act) made for any purpose stated in paragraph (b)(1) of this section, or if its submission could have been required under section 1445 of the Act, 42 U.S.C. 300j–4, regardless of whether such section was cited in any request for the information, or whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207, 2.209, and 2.211 through 2.216 apply without change to information to which this section applies.

(d) [*Reserved*]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies to information to which this section applies, except that the following information is not eligible for confidential treatment: the name and address of any permit applicant or permittee and information which pertains to the existence, absence, or level of contaminants in drinking water is not eligible for confidential treatment.

(f) *Nondisclosure for reasons other than business confidentiality or where disclosure is prohibited by other statute.*

Section 2.210 applies to information to which this section applies, except that information which deals with the existence, absence, or level of contaminants in drinking water shall be available to the public notwithstanding any other provision of this part.

(g) *Disclosure of information relevant to a proceeding.* (1) Under section 1445(d) of the Act, any information to which this section applies may be released by EPA because of the relevance of the information to a proceeding, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information to which this section applies because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2) The provisions of § 2.301(g) (2), (3), and (4) must be followed when making disclosures pursuant to this paragraph (g).

(h) *Disclosure to authorized representatives.* (1) Under section 1445(d) of the Act, EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h)(2) of this section.

(2) The provisions of § 2.301(h) (2) and (3) must be followed when making disclsoures pursuant to this paragraph (h).

§ 2.305 Special rules governing certain information obtained under the Solid Waste Disposal Act, as amended.

(a) *Definitions.* For purposes of this section:

(1) *Act* means the Solid Waste Disposal Act, as amended, including amendments made by the Resource Conservation and Recovery Act of 1976, as amended, 42 U.S.C. 6901 et seq.

(2) *Person* has the meaning given it in section 1004(15) of the Act, 42 U.S.C. 6903(15).

(3) *Hazardous waste* has the meaning given it in section 1004(5) of the Act, 42 U.S.C. 6903(5).

(4) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act including the issuance of administrative orders and the approval or disapproval of plans (e.g. closure plans) submitted by persons subject to regulation under the Act, but not including determinations under this subpart

(b) *Applicability.* This section applies to information provided to or obtained by EPA under section 3001(b)(3)(B), 3007, or 9005 of the Act, 42 U.S.C 6921(b)(3)(B), 6927, or 6991d. Information will be considered to have been provided or obtained under sections 3001(b)(3)(B), 3007, or 9005 of the Act if it was provided in response to a request from EPA made for any of the purposes stated in the Act or if its submission could have been required under those provisions of the Act regardless of whether a specific section was cited as the authority for any request for the information or whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.216 apply without change to information to which this section applies.

(d) *[Reserved]*

(e) *[Reserved]*

(f) *Disclosure of hazardous waste export information.* Information that is required by 40 CFR 262.53(a) which is submitted in notification of intent to export a hazardous waste will be provided to the Department of State and the appropriate authorities in a receiving country regardless of any claims of confidentiality.

(g) *Disclosure of information relevant in a proceeding.* (1) Under sections 3007(b) and 9005(b) of the Act (42 U.S.C. 6927(b) and 6991d(b)), any information to which this section applies may be disclosed by EPA because of the relevance of the information in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (g).

(2) The provisions of § 2.301(g) (2), (3), and (4) must be followed when making disclosures pursuant to this paragraph (g).

(h) *Disclosure to authorized representatives.* (1) Under sections 3001(b)(3)(B), 3007(b), and 9005(b) of the Act (42 U.S.C. 6921(b)(3)(B), 6927(b), and 6991d(b)), EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2) The provisions of § 2.301(h) (2) and (3) must be followed when making disclosures pursuant to this paragraph (h).

(3) At the time any information is furnished to a contractor, subcontractor, or State or local government agency under this paragraph (h), the EPA office furnishing the information to the contractor, subcontractor, or State or local government agency shall notify the contractor, subcontractor, or State or local government agency that the information may be entitled to confidential treatment and that any knowing and willful disclosure of the information may subject the contractor, subcontractor, or State or local government agency and its employees to penalties in section 3001(b)(3)(B), 3007(b)(2), or 9005(b)(1) of the Act (42 U.S.C. 6921(b)(3)(B), 6927(b), or 6991d(b)).

§ 2.306 Special rules governing certain information obtained under the Toxic Substances Control Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Toxic Substances Control Act, 15 U.S.C. 2601 et seq.

(2) *Chemical substance* has the meaning given it in section 3(2) of the Act, 15 U.S.C. 2602(2).

(3) *Health and safety data* (sometimes referred to in this section as *health and safety study*) means the information described in paragraphs (a)(3) (i), (ii), and (iii) of this section with respect to any chemical substance or mixture offered for commercial distribution (including for test marketing purposes and for use in research and development), including but not limited to any chemical substance included on the inventory of chemical substances under section 8 of the Act (15 U.S.C. 2607), or any chemical substance or mixture for which testing is required under section 4 of the Act (15 U.S.C. 2603) or for which notification is required under section 5 of the Act (15 U.S.C. 2604).

(i) Any study of any effect of a chemical substance or mixture on health, on the environment, or on both, including underlying data and epidemiological studies; studies of occupational exposure to a chemical substance or mixture; and toxicological, clinical, and ecological studies of a chemical substance or mixture;

(ii) Any test performed under the Act; and

(iii) Any data reported to, or otherwise obtained by, EPA from a study described in paragraph (a)(3)(i) of this section or a test described in paragraph (a)(3)(ii) of this section. It is intended that the term "health and safety study" be interpreted broadly.

Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical on health or the environment is also included. Any data that bear on the effects of a chemical substance on health or environment would be included. Chemical identity is part of, or underlying data to, a health and safety study.

(4) *[Reserved]*

(5) *Mixture* has the meaning given it in section 3(8) of the Act, 15 U.S.C. 2602(8).

(6) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this subpart.

(7) *Senior Management Official* means an official with management responsibilities for the affected business, such as officials with management responsibilities for the person or persons completing the report, or the manager of environmental programs for the facility or establishments, or for the corporation owning or operating the facility or establishment responsible for certifying similar reports under other environmental regulatory requirements.

(8) *TSCA Inventory* means EPA's comprehensive list of chemical substances which constitute the Chemical Substances Inventory compiled under section 8(b) of the Act. It includes substances reported under 40 CFR part 710, subpart A and substances reported under 40 CFR part 720 for which a Notice of Commencement of Manufacture or Import has been received under 40 CFR 720.120.

(b) *Applicability.* This section applies to all information submitted to EPA for the purpose of satisfying some requirement or condition of the Act or of regulations which implement the Act, including information originally submitted to EPA for some other purpose and either relied upon to avoid some requirement or condition of the Act or incorporated into a submission in order to satisfy some requirement or condition of the Act or of regulations which implement the Act. Information will be considered to have been provided under the Act if the information could have been obtained under authority of the Act, whether the Act was cited as authority or not, and whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201, 2.202, 2.206, 2.207, and §§ 2.210 through 2.216 apply without change to information to which this section applies.

(d) *Method of asserting business confidentiality claim; effect of failure to assert claim at time of submission.* Section 2.203 applies, except that—

(1) An owner, operator or senior management official, as defined in paragraph (a)(7) of this section, shall sign all business confidentiality claims to which this section applies;

(2) With respect to confidentiality claims for specific chemical identity in submissions of Records and Reports of Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment in accordance with section 8(c) of the Act and 40 CFR part 717, Health and Safety Data Reports in accordance with section 8(d) of the Act and 40 CFR part 716, or notices of substantial risk in accordance with section 8(e) of the Act, where the chemical substance is listed on the TSCA Inventory—

(i) The affected business must file with the document submission detailed written answers to the following 11 questions signed and dated by a senior management official, as defined in paragraph (a)(7) of this section:

(A) What harmful effects to your competitive position, if any, do you think would result from the identity of the chemical substance being disclosed in connection with reporting under this subpart?

(B) How long should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(C) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential?

(D) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured or imported for a commercial purpose by anyone?

(E) Is the fact that the chemical substance is being manufactured or imported for a commercial purpose publicly available, for example in technical journals, libraries, or State, local, or Federal agency public files?

(F) What measures have you taken to prevent undesired disclosure of the fact that this chemical substance is being manufactured or imported for a commercial purpose?

(G) To what extent has the fact that this chemical substance is manufactured or imported for commercial purposes been revealed to others? What precautions have been taken regarding these disclosures? Have there been public disclosures or disclosures to competitors?

(H) Does this particular chemical substance leave the site of manufacture in any form, as product, effluent, emission, etc.? If so, what measures have you taken to guard against discovery of its identity?

(I) If the chemical substance leaves the site in a product that is available to the public or your competitors, can the substance be identified by analysis of the product?

(J) For what purpose do you manufacture or import the substance?

(K) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, please attach copies of such determinations.

(ii) If any of the information contained in the answers to the questions is asserted to contain confidential business information, the submitter must mark that information as "trade secret," "confidential" or other appropriate designation.

(iii) If the substantiation required under paragraph (d)(2)(i) of this section is not submitted at the time a confidentiality claim is asserted, EPA will deem the claim for chemical identity waived and may make the identity public without further notice to the submitter.

(3) With respect to information collected pursuant to the following provisions from subchapter R of this chapter, the provisions of § 2.203 are modified as provided below. (Each provision is identified by subject matter and states the subject of the difference from § 2.203.)

(i) Information submitted pursuant to 40 CFR part 704, subpart A (Reporting and Recordkeeping Requirements—General Reporting and Recordkeeping Provisions for Section 8(a) Information-Gathering Rules) is subject to § 704.7 of this chapter (method of asserting claims; certification requirement; effect of failure to properly assert claims).

(ii) Information submitted pursuant to 40 CFR part 704, subpart C (Reporting and Recordkeeping Requirements—CAIR: Comprehensive Assessment Information Rule—General Reporting and Recordkeeping Provisions) is subject to § 704.219 (method of asserting claims; substantiating claims; effect of failure to properly assert or substantiate claims).

(iii) Information submitted pursuant to 40 CFR part 710, subpart A (Inventory Reporting Regulations—Compilation of the Inventory) is subject to § 710.7

(method of asserting claims; substantiating claims; effect of failure to properly assert or substantiate claims).

(iv) Information submitted pursuant to 40 CFR part 710, subpart B (Inventory Reporting Regulations—Partial Updating of the Inventory Data Base) is subject to § 710.38 of this chapter (method of asserting claims; limitation on claims for chemical identity; substantiating claims; effect of failure to properly assert or substantiate claims).

(v) Information submitted pursuant to 40 CFR part 712 (Chemical Information Rules—General Provisions) is subject to § 712.15 of this chapter (certification requirement; effect of failure to properly assert or certify claims).

(vi) Information submitted pursuant to 40 CFR part 716 (Health and Safety Data Reporting) is subject to § 716.55 (method of asserting claims; sanitized version of document required; effect of failure to provide sanitized copy).

(vii) Information submitted pursuant to 40 CFR part 717 (Records and Reports of Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment) is subject to § 717.19 of this chapter (method of asserting claims; sanitized copy of document required; effect of failure to provide sanitized copy).

(viii) Information submitted pursuant to 40 CFR part 720 (Premanufacture Notification) is subject to—

(A) Section 720.80 of this chapter (method of asserting claims; effect of failure to assert claim);

(B) Section 720.85(a) of this chapter (claims for confidentiality of chemical identity applicable to the period prior to commencement of manufacture or import; generic name requirement);

(C) Section 720.85(b) of this chapter (claims for confidentiality of chemical identity applicable to the period after commencement of manufacture or import; method of asserting claims; substantiation requirement; effect of failure to substantiate properly; generic name requirement);

(D) Section 720.87 of this chapter (method of asserting claims; generic use requirement);

(E) Section 720.90 of this chapter (method of asserting claims; substantiation requirement); and

(F) Section 720.102 of this chapter (reassertion and substantiation of claims for chemical identity; effect of failure to reassert or substantiate claims).

(ix) Information submitted pursuant to 40 CFR 723.50 (Premanufacture Notice Exemptions—Chemical Substances Manufactured in Quantities of 1,000 Kilograms or Less per Year—Exemption Notice) is subject to § 723.50 (e)(1)(E) and (k)(2) of this chapter (generic name requirement).

(x) Information submitted pursuant to 40 CFR 723.250 (Premanufacture Notice Exemptions—Polymers) is subject to paragraph (d)(3)(viii)(A)–(F) of § 2.306.

(xi) Information submitted pursuant to 40 CFR part 761 (Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions—Notification of PCB Waste Activity) is subject to § 761.205(a)(4)(viii) (certain information will not be afforded confidential treatment unless the submitter makes a sufficient showing of reasons for confidential treatment; timing of asserting claims).

(xii) Information submitted pursuant to 40 CFR part 763, subpart D (Reporting Commercial and Industrial Uses of Asbestos) is subject to § 763.74 (method of asserting claims: certification requirement).

(xiii) Information submitted pursuant to 40 CFR part 763, subpart I (Asbestos—Prohibition on The Manufacture, Importation, Processing and Distribution in Commerce of Certain Asbestos-Containing Products; Labeling Requirements) is subject to § 763.179 (method of asserting claims; timing of asserting claims; sanitized copy of document required; effect of failure to submit a sanitized copy; substantiation requirement; effect of failure to substantiate).

(xiv) Information submitted pursuant to 40 CFR part 790 (Procedures Governing Testing Consent Agreements and Test Rules) is subject to § 790.7 (method of asserting claims; timing of asserting claims; substantiation requirement; effect of failure to substantiate).

(e) *Initial action by EPA office.* Section 2.204 applies to information to which this section applies, except that the provisions of paragraph (e)(3) of this section regarding the time allowed for seeking judicial review shall be reflected in any notice furnished to a business under § 2.204(d)(2).

(f) *Final confidentiality determination by EPA legal office.* Section 2.205 applies to information to which this section applies, except that—

(1) In addition to the statement prescribed by the second sentence of § 2.205(f)(2), the notice of denial of a business confidentiality claim shall state that under section 20(a) of the Act, 15 U.S.C. 2619, the business may commence an action in an appropriate Federal district court to prevent disclosure.

(2) The following sentence is substituted for the third sentence of § 2.205(f)(2): "With respect to EPA's implementation of the determination the notice shall state that (subject to § 2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the date of the business' receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business' commencement of an action in a Federal court to obtain judicial review of the determination and to obtain preliminary injunctive relief against disclosure."; and

(3) Notwithstanding § 2.205(g), the 31 calendar day period prescribed by § 2.205(f)(2), as modified by paragraph (e)(3) of this section, shall not be shortened without the consent of the business.

(g) [*Reserved*]

(h) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies, except that health and safety data are not eligible for confidential treatment. Notwithstanding the preceding sentence, § 2.208 applies to—

(1) Health and safety data governed by § 716.55(a) (3) or (4), § 720.85(a)(ii), § 720.90, or § 723.250(g)(9) of subchapter R of this chapter; and

(2) Health and safety data whose disclosure would—

(i) In the case of a chemical substance or mixture, disclose processes used in the manufacturing or processing of the chemical substance or mixture; or

(ii) In the case of a mixture, disclose the portion of the mixture comprised by any of the chemical substances in the mixture.

(i) *Disclosure in special circumstances.* Section 2.209 applies to information to which this section applies, except that—

(1) The following two additional provisions apply to § 2.209(c):

(i) The official purpose for which the information is needed must be in connection with the agency's duties under any law for protection of health or the environment or for specific law enforcement purposes; and

(ii) EPA notifies the other agency that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the officers and employees of the other agency to the penalties in section 14(d) of the Act (15 U.S.C. 2613(d)).

(2) Information governed by part 707, subpart D of this chapter (Chemical Imports and Exports—Notices of Export Under section 12(b) of the Act) may be

disclosed to foreign governments pursuant to § 707.75(c) of this chapter.

(3) Information submitted pursuant to part 710, subpart A of this chapter (Inventory Reporting Regulations—Compilation of the Inventory) may be disclosed to a *bona fide* requestor pursuant to § 710.7 of this chapter.

(4) Information submitted pursuant to part 720 of this chapter (Premanufacture Notification) may be disclosed to a *bona fide* requestor pursuant to § 720.85 of this chapter.

(5) Information submitted pursuant to part 721 of this chapter (Significant New Uses of Chemical Substances) may be disclosed to a *bona fide* requestor pursuant to §§ 721.555, 721.557, and 721.575 of this chapter.

(6) Information submitted pursuant to part 723 of this chapter (Premanufacture Notice Exemptions—Polymers) may be disclosed to a *bona fide* requestor pursuant to § 723.250(g)(7) of this chapter.

(j) *Disclosure of information relevant in a proceeding.* (1) Under section 14(a)(4) of the Act (15 U.S.C. 2613(a)(4)), any information to which this section applies may be disclosed by EPA when the information is relevant in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. However, any such disclosure shall be made in a manner that preserves the confidentiality of the information to the extent practicable without impairing the proceeding. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (j).

(2) The provisions of § 2.301(g) (2), (3), and (4) must be followed when making disclosures pursuant to this paragraph (j).

(k) *Disclosure of information to contractors and subcontractors.* (1) Under section 14(a)(2) of the Act (15 U.S.C. 2613(a)(2)), any information to which this section applies may be disclosed by EPA to a contractor or subcontractor of the United States performing work under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Subject to the limitations in this paragraph (j), information to which this section applies may be disclosed

(i) To a contractor or subcontractor with EPA, if the EPA program office managing the contract first determines in writing that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract; or

(ii) To a contractor or subcontractor with an agency other than EPA, if the EPA program office which provides the information to that agency, contractor, or subcontractor first determines in writing, in consultation with the General Counsel, that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract.

(2) The provisions of § 2.301(h)(2) (ii) and (iii) must be followed when making disclosures pursuant to this paragraph (k).

(3) At the time any information is furnished to a contractor or subcontractor under this paragraph (k), the EPA office furnishing the information to the contractor or subcontractor shall notify the contractor or subcontractor that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the contractor or subcontractor and its employees to the penalties in section 14(d) of the Act (15 U.S.C. 2613(d)).

(l) *Disclosure of information when necessary to protect health or the environment against an unreasonable risk of injury.* (1) Under section 14(a)(3) of the Act (15 U.S.C. 2613(a)(3)), any information to which this section applies may be disclosed by EPA when disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment. However, any disclosure shall be made in a manner that preserves the confidentiality of the information to the extent not inconsistent with protecting health or the environment against the unreasonable risk of injury. Disclosure of information to which this section applies because of the need to protect health or the environment against an unreasonable risk of injury shall be made only in accordance with paragraph (k) of this section.

(2) If any EPA office determines that there is an unreasonable risk of injury to health or the environment and that to protect health or the environment against the unreasonable risk of injury it is necessary to disclose information to which this section applies that otherwise might be entitled to confidential treatment under this subpart, the EPA office shall notify the General Counsel in writing of the nature of the unreasonable risk of injury, the extent of the disclosure proposed, how the proposed disclosure will serve to protect health or the environment against the unreasonable risk of injury, and the proposed date of disclosure. Such notification shall be made as soon as practicable after discovery of the unreasonable risk of injury. If the EPA office determines that the risk of injury is so imminent that it is impracticable to furnish written notification to the General Counsel, the EPA office shall notify the General Counsel orally.

(3) Upon receipt of notification under paragraph (k)(2) of this section, the General Counsel shall make a determination in writing whether disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury. The General Counsel shall also determine the extent of disclosure necessary to protect against the unreasonable risk of injury as well as when the disclosure must be made to protect against the unreasonable risk of injury.

(4) If the General Counsel determines that disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury, the General Counsel shall furnish notice to each affected business of the contemplated disclosure and of the General Counsel's determination. Such notice shall be made in writing by certified mail, return receipt requested, at least 15 days before the disclosure is to be made. The notice shall state the date upon which disclosure will be made. However, if the General Counsel determines that the risk of injury is so imminent that it is impracticable to furnish such notice 15 days before the proposed date of disclosure, the General Counsel may provide notice by means that will provide receipt of the notice by the affected business at least 24 hours before the disclosure is to be made. This may be done by telegram, telephone, or other reasonably rapid means.

(m) *Sunset provisions.* (1) Pursuant to §§ 2.216, 720.85, 720.90, and 720.102, claims for confidentiality of chemical identity in Premanufacture Notifications expire upon commencement of manufacture or export unless reasserted in the Notice of Commencement.

(2) Pursuant to §§ 2.216 and 723.250(g) (7), (9), and (11), claims for confidentiality of chemical identity in Polymer Exemption Applications expire upon commencement of manufacture or export unless reasserted in the Notice of Commencement.

(3) Notwithstanding § 2.216(a), the provisions of this paragraph (m) apply to claims for confidentiality of chemical identity in Premanufacture Notifications

and Polymer Exemption Applications, regardless of whether they were submitted on or after [insert effective date of final rule].

§ 2.307 Special rules governing certain information obtained under the Federal Insecticide, Fungicide and Rodenticide Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. 136 et seq., and its predecessor, 7 U.S.C. 135 et seq.

(2) *Applicant* means any person who has submitted to EPA (or to a predecessor agency with responsibility for administering the Act) a registration statement or application for registration under the Act of a pesticide or of an establishment.

(3) *Registrant* means any person who has obtained registration under the Act either of a pesticide or of an establishment.

(4) *Qualified person* means any person whose presence or services are required for the prevention or mitigation of imminent harm to persons, property or the environment, and who requires access to confidential information in order to perform his or her duties in that capacity.

(5) *Safety and efficacy data* means all information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism. Data concerning a pesticide which has never been registered do not constitute safety and efficacy data.

(b) *Applicability.* This section applies to all information submitted to EPA by an applicant or registrant for the purpose of satisfying some requirement or condition of the Act or of regulations which implement the Act, including information originally submitted to EPA for some other purpose but incorporated by the applicant or registrant into a submission in order to satisfy some requirement or condition of the Act or of regulations which implement the Act. This section does not apply to information supplied to EPA by a petitioner in support of a petition for a tolerance under 21 U.S.C. 346a(d), unless the information is also described by the first sentence of this paragraph.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.203, 2.206, 2.207, 2.210 through 2.212, and 2.214 through 2.216 apply without change to information to which this section applies.

(d) *Method of asserting business confidentiality claim.* Section 2.203 applies to information to which this section applies, except that—

(1) Information submitted pursuant to part 154, Special Review Procedures, shall be subject to the requirements of § 154.15(c) of this chapter.

(2) Information submitted pursuant to part 155, Registration Standards, shall be subject to the requirements of § 155.30(c) of this chapter.

(3) Information submitted pursuant to part 158, Data Requirements for Registration, shall be subject to the requirements of § 158.33 of this chapter.

(4) Analytical methods submitted pursuant to § 158.240 of this chapter and used to enforce residue limits for emergency exemptions, temporary tolerances and permanent tolerances must be available for use by enforcement agencies and thus may not be claimed as confidential business information.

(e) *Initial action by EPA office.* Section 2.204 applies to information to which this section applies, except that the provisions of paragraph (e) of this section regarding the time allowed for seeking judicial review shall be reflected in any notice furnished to a business under § 2.204(d)(2).

(f) *Final confidentiality determination by EPA legal office.* Section 2.205 applies to information to which this section applies, except that—

(1) In addition to the statement prescribed by the second sentence of § 2.205(f)(2), the notice of denial of a business confidentiality claim shall state that under section 10(c) of the Act, 7 U.S.C. 136h(c), the business may commence an action in an appropriate Federal district court for a declaratory judgment;

(2) The following sentence is substituted for the third sentence of § 2.205(f)(2): "With respect to EPA's implementation of the determination, the notice shall state that (subject to § 2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the date of the business' receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business' commencement of an action in a Federal court to obtain judicial review of the determination or to obtain a declaratory judgment under section 10(c) of the Act and to obtain preliminary injunctive relief against disclosure."; and

(3) Notwithstanding § 2.205(g), the 31 calendar day period prescribed by § 2.205(f)(2), as modified by paragraph (e)(3) of this section, shall not be shortened without the consent of the business.

(g) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies except as provided in this paragraph (g). No information to which this section applies is voluntarily submitted information.

(1) Safety and efficacy data are not eligible for confidential treatment. Notwithstanding the preceding sentence, § 2.208 applies where an affected business has shown that disclosure of the information would disclose one or more of the following types of information:

(i) Manufacturing or quality control processes;

(ii) Details of any methods for testing, detection, or measuring the quantity of any deliberately added inert ingredient of a pesticide; or

(iii) The identity or percentage quantity of any deliberately added inert ingredient of a pesticide.

(2) The following information on the purchaser acknowledgement statement submitted pursuant to section 17(a)(2) of the Act is not eligible for confidential treatment, unless the purchaser acknowledgement statement pertains to a research and development product (in which case § 2.208 applies):

(i) The identity of the importing country;

(ii) The identity of the producer of the unregistered pesticide;

(iii) The identity of the exporting company;

(iv) The name of the unregistered pesticide product; and

(v) The name of the active ingredient.

(h) *Disclosure in special circumstances.* (1) Section 2.209 applies without change to information to which this section applies. In addition, under section 12(a)(2)(D) of the Act, 7 U.S.C. 136j(a)(2)(D), EPA possesses authority to disclose any information to which this section applies to physicians, pharmacists, and other qualified persons needing such information for the performance of their duties, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority under section 12(a)(2)(D) of the Act may be exercised

in accordance with paragraph (h)(2) or (h)(3) of this section.

(2) Information to which this section applies may be disclosed (notwithstanding the fact that it might otherwise be entitled to confidential treatment under this subpart) to physicians, pharmacists, hospitals, veterinarians, law enforcement personnel, or Federal, State, or local governmental agencies with responsibilities for protection of public health, and to employees of any such persons or agencies, or to other qualified persons, when and to the extent that disclosure is necessary in order to treat illness or injury or to prevent imminent harm to persons, property, or the environment, in the opinion of the Administrator or his designee.

(3)(i) Information to which this section applies may be disclosed (notwithstanding the fact that it otherwise might be entitled to confidential treatment under this subpart)—

(A) To a contractor or subcontractor with EPA, if the EPA program office managing the contract first determines in writing that such disclosure is necessary for the satisfactory performance of a contract or subcontract in connection with the Act; or

(B) To a contractor or subcontractor with a Federal agency other than EPA, if the EPA program office which provides the information to that agency, contractor, or subcontractor first determines in writing, in consultation with the General Counsel, that such disclosure is necessary for the satisfactory performance of a contract or subcontract in connection with the Act.

(ii) The provisions of § 2.301(h)(2) (ii) and (iii) must be followed when making disclosures pursuant to this paragraph (h)(3).

(iii) At the time any information is furnished to a contractor or subcontractor under this paragraph (h)(3), the EPA office furnishing the information to the contractor or subcontractor shall notify the contractor or subcontractor that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the contractor or subcontractor and its employees to the penalties in section 10(f) of the Act (7 U.S.C. 136h(f)).

(iv) Contractors receiving information to which this section applies will be required to follow the security procedures established in the "FIFRA Information Security Manual," which is available through the Office of Pesticide Programs, Information Services Branch.

(v) For purposes of this section, the term "contract" includes grants and cooperative agreements under the Environmental Programs Assistance Act of 1984 (Pub. L. 98–313), and the term "contractor" includes grantees and cooperators under the Environmental Programs Assistance Act of 1984.

(4) Information to which this section applies, and which relates to formulas of products, may be disclosed at any public hearing under the Act. Prior to such disclosure, EPA will follow the procedures set forth in § 2.301(g)(3) and (4), which are incorporated here by reference.

(5) Information to which this section applies, and which relates to formulas of products, may be disclosed in findings of fact issued by the Administrator under the Act. No information shall be made available to the public under this paragraph (h)(5) until

(i) The official responsible for issuing the findings of fact has made a written finding that disclosure is necessary to carry out the provisions of the Act;

(ii) EPA has notified the affected business by certified mail, return receipt requested, of the Agency's intent to disclose the information; and

(iii) Thirty calendar days have passed since the business' receipt of the notice required under paragraph (h)(5)(ii) of this section.

(6) Information to which this section applies, and which concerns production, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment may be disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment. In proposing to disclose such information, EPA will follow the procedures set forth in § 2.301(g)(2)-(4), except that before disclosing the information, EPA will make a determination that the disclosure is necessary in the public interest, and will give all affected businesses thirty days advance notice by certified mail, return receipt requested. During the thirty day period, the submitter will have the opportunity to seek judicial review.

(7)(i) Under section 10(d)(1) of the Act (7 U.S.C 136(d)(1)), any safety and efficacy data (as defined in paragraph (a)(5) of this section) to which this section applies and which falls within one of the classes of information defined by paragraph (g) (1), (2), or (3) of this section may be disclosed by EPA when disclosure is necessary to protect against an unreasonable risk of injury to health or the environment. However, any disclosure shall be made in a manner that preserves the confidentiality of the information to the extent not inconsistent with protecting health or the environment against the unreasonable risk of injury. Disclosure of information to which this section applies because of the need to protect health or the environment against an unreasonable risk of injury shall be made only in accordance with this paragraph (h)(7).

(ii) The provisions of § 2.306(l) (2) and (3) must be followed when making disclosures pursuant to this paragraph (h)(7).

(iii) If the General Counsel determines that disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury, the General Counsel shall furnish notice to each affected business of the contemplated disclosure and of the General Counsel's determination. Such notice shall be made in writing by certified mail, return receipt requested, at least 30 days before the disclosure is to be made. The notice shall state the date upon which disclosure will be made. However, if the General Counsel determines that the risk of injury is so imminent that it is impracticable to furnish such notice 30 days before the proposed date of disclosure, the General Counsel may provide notice by means that will provide receipt of the notice by the affected business at least 10 days before the disclosure is to be made. This may be done by telegram, telephone, or other reasonably rapid means.

(8) Information required to be produced pursuant to part 164 (rules of practice governing regulatory hearings under the Act) and which any party to the proceeding claims is a trade secret or commercial or financial information (other than information relating to the formulas of a pesticide) shall be subject to the requirements of § 164.4(c).

(i) *Restriction on disclosure to foreign or multinational entities*

(1) A request (including any request submitted pursuant to subpart A of this part) for data obtained from an applicant or registrant under the Act must be made in writing, and must be accompanied by a signed affirmation as required by section 10(g)(1) of the Act. The affirmation must contain the language specified in paragraph (i)(2) of this section. If EPA receives a request that is not accompanied by a signed affirmation, EPA will return the request unprocessed (if the request also includes information not within the scope of this paragraph (i), the remainder of the request will be handled pursuant to the procedures in subpart A of this part). This paragraph

(i) does not apply to reviews of data which were prepared by EPA personnel or under an EPA-funded contract and which do not reveal the full methodology and complete results of the study, test, or experiment, and all explanatory information necessary to understand the methodology or interpret the results.

(2) The requestor must sign the following affirmation:

I have requested access to data submitted by an applicant or registrant under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) to the Environmental Protection Agency. I hereby affirm:

That I do not seek access to the data for the purpose of delivering it or offering it for sale to any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or its agents or employees; and

That I will not purposefully deliver or negligently cause the data to be delivered to any such business or entity or its agents or employees. I am aware that I may be subject to criminal penalties under 18 U.S.C 1001 if I have made any statement of material facts knowing that such statement is false or if I willfully conceal any material fact.

(Signature, Name, Address, Organization or Affiliation, Client.)

(3) The first time EPA discloses data submitted by a specific applicant or registrant under the Act in response to a written request by a member of the public, EPA will provide written notice to the applicant or registrant. The notice will include a copy of the affirmation and a listing of the data disclosed, and will advise the applicant or registrant that EPA maintains a file of affirmations and data disclosure listings. Copies of future affirmations and data disclosure listings may be obtained by the appropriate registrants and applicants by request to EPA.

(4) Notwithstanding any other provision of this paragraph (i), data submitted by an applicant or registrant under the Act which is not subject to a claim of confidentiality may be disclosed to any person in connection with a public proceeding where the information is relevant to a determination by the Administrator as to whether a pesticide, or an ingredient of a pesticide, causes unreasonable adverse effects on health or the environment. EPA will disclose the information only after a finding by the appropriate official that the information is relevant to such a determination. No advance notice will be given of such disclosures.

(j) *Designation by business of addressee for notices and inquiries.* Section 2.213 applies to information to which this section applies, except that designations by registrants and applicants submitting information pursuant to part 152 of this chapter shall be made pursuant to § 152.50(b) (2) and (3) of this chapter.

(k) *Availability of material in support of registration and reviews of pesticide data.* Regardless of any claims of confidentiality—

(1) Within 30 days after registration under the Act, EPA will make available for public inspection, by request, and without notice to affected businesses, the materials required by subpart E of part 152 of this chapter to be submitted with an application for registration. Materials that will be publicly available include an applicant's list of data requirements, the method used by the applicant to demonstrate compliance for each data requirement, and the applicant's citations of specific studies in the Agency's possession if applicable; and

(2) EPA may make available to the public, without notice to affected businesses, reviews of safety and efficacy data which do not contain (or from which has been deleted) any information, the disclosure of which would in turn disclose—

(i) Information described in paragraphs (g)(1) (i)–(iii) of this section; or

(ii) Unpublished information concerning the production, distribution, sale, or inventories of a pesticide.

§ 2.308 Special rules governing certain information obtained under the Federal Food, Drug and Cosmetic Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301 et seq.

(2) *Petition* means a petition for the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting the pesticide chemical from the necessity of a tolerance, pursuant to section 408(d) of the Act, 21 U.S.C. 346a(d).

(3) *Petitioner* means a person who has submitted a petition to EPA (or to a predecessor agency).

(b) *Applicability.* (1) This section applies only to business information submitted to EPA (or to an advisory committee established under the Act) by a petitioner, solely in support of a petition which has not been acted on by the publication by EPA of a regulation establishing a tolerance for a pesticide chemical or exempting the pesticide chemical from the necessity of a tolerance, as provided in section 408(d) (2) or (3) of the Act, 21 U.S.C. 346a(d) (2) or (3).

(2) Section 2.307, rather than this section, applies to information described by the first sentence of § 2.307(b) (material incorporated into submissions in order to satisfy the requirements of the Federal Insecticide, Fungicide and Rodenticide Act, as amended), even though such information was originally submitted by a petitioner in support of a petition.

(3) This section does not apply to information gathered by EPA under a proceeding initiated by EPA to establish a tolerance under section 408(e) of the Act, 21 U.S.C. 346a(e).

(c) *Basic rules which apply without change.* Sections 2.201, 2.202, 2.206, 2.207, and 2.210 through 2.216 apply without change to information to which this section applies.

(d) *Effect of submission of information without claim.* Section 2.203 (a), (b), and (c)(1) apply without change to information to which this section applies, except that summaries of petitions required under § 177.102(j) of this chapter may not be claimed as confidential. Section 2.203(c)(2) does not apply to information to which this section applies. A petitioner's failure to assert a claim when initially submitting a petition shall not constitute a waiver of any claim the petitioner may have.

(e) *Initial action by EPA office.* Section 2.204 applies to information to which this section applies, except that—

(1) Unless the EPA office has on file a written waiver of petitioner's claim, a petitioner shall be regarded as an affected business, a petition shall be treated as if it were covered by a business confidentiality claim, and an EPA office acting under § 2.204(d) shall determine that the information in the petition is or may be entitled to confidential treatment and shall take action in accordance with § 2.204(d)(1);

(2) In addition to other required provisions of any notice furnished to a petitioner under § 2.204(e), such notice shall state that—

(i) Section 408(f) of the Act, 21 U.S.C. 346a(f), affords absolute confidentiality to information to which this section applies, but after publication by EPA of a regulation establishing a tolerance (or exempting the pesticide chemical from the necessity of a tolerance) neither the Act nor this section affords any protection to the information;

(ii) Information submitted in support of a petition which is also incorporated into a submission in order to satisfy a requirement or condition of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. 136 et seq., is regarded by EPA as being governed,

with respect to business confidentiality, by § 2.307 rather than by this section;

(iii) Although it appears that this section may apply to the information at this time, EPA is presently engaged in determining whether for any reason the information is entitled to confidential treatment or will be entitled to such treatment if and when this section no longer applies to the information; and

(iv) Information determined by EPA to be covered by this section will not be disclosed for as long as this section continues to apply, but will be made available to the public thereafter (subject to § 2.210) unless the business furnishes timely comments in response to the notice.

(f) *Final confidentiality determination by EPA legal office.* Section 2.205 applies to information to which this section applies, except that—

(1) In addition to the circumstances mentioned in § 2.205(f)(1), notice in the form prescribed by § 2.205(f)(2) shall be furnished to each affected business whenever information is found to be entitled to confidential treatment under section 408(f) of the Act but not otherwise entitled to confidential treatment. With respect to such cases, the following sentences shall be substituted for the third sentence of § 2.205(f)(2): "With respect to EPA's implementation of the determination, the notice shall state that (subject to § 2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the business' receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business' commencement of an action in a Federal court to obtain judicial review of the determination and to obtain preliminary injunctive relief against disclosure; provided, that the information will not be made available to the public for so long as it is entitled to confidential treatment under section 408(f) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(f)."; and

(2) Notwithstanding § 2.205(g), the 31 calendar day period prescribed by § 2.205(f)(2), as modified by paragraph (f)(2) of this section, shall not be shortened without the consent of the business.

(g) *[Reserved]*

(h) *Substantive criteria for use in confidentiality determinations.* Section 2.208 does not apply to information to which this section applies. Such information shall be determined to be entitled to confidential treatment for so long as this section continues to apply to it.

(i) *Disclosure in special circumstances.* (1) Section 2.209 applies to information to which this section applies. In addition, under Section 408(f) of the Act, 21 U.S.C. 346a(f), EPA is authorized to disclose the information to other persons. Such authority under section 408(f) of the Act may be exercised only in accordance with paragraph (i)(2) or (i)(3) of this section.

(2) Information to which this section applies may be disclosed (notwithstanding the fact that it otherwise might be entitled to confidential treatment under this subpart) to a person under contract to EPA to perform work for EPA in connection with the Act, with the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, or regulations which implement either such Act, if the EPA program office managing the contract first determines in writing that such disclosure is necessary in order that the contractor may carry out the work required by the contract. Any such disclosure to a contractor shall be made only in accordance with the procedures and requirements of § 2.301(h)(2)(ii) and (h)(2)(iii).

(3) Information to which this section applies may be disclosed by EPA to an advisory committee in accordance with section 408(d) of the Act, 21 U.S.C. 346a(d).

§ 2.309 Special rules governing certain information obtained under the Marine Protection, Research and Sanctuaries Act of 1972.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Marine Protection, Research and Sanctuaries Act of 1972, 33 U.S.C. 1401 et seq.

(2) *Permit* means any permit applied for or granted under the Act.

(3) *Application* means an application for a permit.

(b) *Applicability.* This section applies to all information provided to or obtained by EPA as a part of any application or in connection with any permit.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207 and 2.209 through 2.216 apply without change to information to which this section applies.

(d) *Substantive criteria for use in confidentiality determinations.* Section 2.208 does not apply to information to which this section applies. Pursuant to section 104(f) of the Act, 33 U.S.C. 1414(f), no information to which this section applies is eligible for confidential treatment.

§ 2.310 Special rules governing certain information obtained under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

(a) *Definitions.* For purposes of this section:

(1) *Act* means the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, including amendments made by the Superfund Amendments and Reauthorization Act of 1986, 42 U.S.C. 9601, et seq.

(2) *Person* has the meaning given it in section 101(21) of the Act, 42 U.S.C. 9601(21).

(3) *Facility* has the meaning given it in section 101(9) of the Act, 42 U.S.C. 9601(9).

(4) *Hazardous substance* has the meaning given it in section 101(14) of the Act, 42 U.S.C. 9601(14).

(5) *Release* has the meaning given it in section 101(22) of the Act, 42 U.S.C. 9601(22).

(6) *Proceeding* means any rulemaking or adjudication conducted by EPA under the Act or under regulations which implement the Act (including the issuance of administrative orders under section 106 of the Act and cost recovery pre-litigation settlement negotiations under sections 107 or 122 of the Act), any cost recovery litigation under section 107 of the Act, or any administrative determination made under section 104 of the Act, but not including determinations under this subpart.

(b) *Applicability.* This section applies only to information provided to or obtained by EPA under section 104 of the Act, 42 U.S.C. 9604, by or from any person who stores, treats, or disposes of hazardous wastes; or where necessary to ascertain facts not available at the facility where such hazardous substances are located, by or from any person who generates, transports, or otherwise handles or has handled hazardous substances, or by or from any person who performs or supports removal or remedial actions pursuant to section 104(a) of the Act. Information will be considered to have been provided or obtained under section 104 of the Act if it was provided in response to a request from EPA or a representative of EPA made for any of the purposes stated in section 104, if it was provided pursuant to the terms of a contract, grant or other agreement to perform work pursuant to section 104, or if its submission could have been required under section 104, regardless of whether section 104 was cited as authority for any request for the information or whether the information

was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.216 apply without change to information to which this section applies.

(d) *[Reserved]*

(e) *[Reserved]*

(f) *[Reserved]*

(g) *Disclosure of information relevant to a proceeding.* (1) Under section 104(e)(7)(A) of the Act (42 U.S.C. 9604(e)(7)(A)) any information to which this section applies may be disclosed by EPA because of the relevance of the information in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (g).

(2) The provisions of § 2.301(g)(2) must be followed when making disclosures pursuant to paragraph (g) of this section.

(3) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, except with respect to litigation conducted by a Federal court, information to which this section applies which may be entitled to confidential treatment may be made available to the public, or to one or more parties of record to the proceeding, upon EPA's initiative, under this paragraph (g)(3). An EPA office proposing disclosure of information under this paragraph (g)(3), shall so notify the presiding officer in writing. Upon receipt of such a notification, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(3) has been proposed, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed under this paragraph (g)(3) only if, after consideration of any timely comments submitted by the business, the EPA office determines in writing that, for reasons directly associated with the conduct of the proceeding, the contemplated disclosure would serve the public interest, and the presiding officer determines in writing that the information is relevant to a matter in controversy in the proceeding. The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information for confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to the public or to one or more of the parties of record to the proceeding.

(4) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, except with respect to litigation conducted by a Federal court, information to which this section applies which may be entitled to confidential treatment may be made available to one or more parties of record to the proceeding, upon request of a party, under this paragraph (g)(4). A party of record seeking disclosure of information shall direct his request to the presiding officer. Upon receipt of such a request, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(4) has been requested, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed to a party of record under this paragraph (g)(4) only if, after consideration of any timely comments submitted by the business, the presiding officer determines in writing both that the party of record has satisfactorily shown that with respect to a significant matter which is in controversy in the proceeding, the party's ability to participate effectively in the proceeding will be significantly impaired unless the information is disclosed to him, and that any harm to an affected business that would result from the disclosure is likely to be outweighed by the benefit to the proceeding and the public interest that would result from the disclosure. The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information for confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to one or more of the parties of record to the proceeding.

(5) In connection with cost recovery pre-litigation settlement negotiations under section 107 or 122 of the Act (42 U.S.C. 9607, 9622), any information to which this section applies that may be entitled to confidential treatment may be made available to potentially responsible parties pursuant to a contractual agreement to protect the information.

(6) In connection with any cost recovery proceeding under section 107 of the Act involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, any information to which this section applies that may be entitled to confidential treatment may be made available to one or more parties of record to the proceeding, upon EPA's initiative, under this paragraph (g)(6). Such disclosure must be made pursuant to a stipulation and protective order signed by all parties to whom disclosure is made and by the presiding officer.

(h) *Disclosure to authorized representatives.* (1) Under section 104(e)(7) of the Act (42 U.S.C. 9604(e)(7)), EPA possesses authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart.

(2) The provisions of § 2.301(h)(2) and (h)(3) must be followed when making disclosures pursuant to paragraph (h) of this section.

(3) At the time any information is furnished to a contractor, subcontractor, or State or local government agency under this paragraph (h), the EPA office furnishing the information to the contractor, subcontractor, or State or local government agency shall notify the contractor, subcontractor, or State or local government agency that the information may be entitled to confidential treatment and that any knowing and willful disclosure of the information may subject the contractor, subcontractor, or State or local government agency and its employees to penalties in section 104(e)(7)(B) of the Act (42 U.S.C. 9604(e)(7)(B)).

§ 2.311 Special rules governing certain information obtained under the Motor Vehicle Information and Cost Savings Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Motor Vehicle Information and Cost Savings Act, as amended, 15 U.S.C. 1901 *et seq.*

(2) *Average fuel economy* has the meaning given it in section 501(4) of the Act, 15 U.S.C. 2001(4).

(3) *Fuel economy* has the meaning given it in section 501(6) of the Act, 15 U.S.C. 2001(6).

(4) *Fuel economy data* means any measurement or calculation of fuel

economy for any model type and average fuel economy of a manufacturer under section 503(d) of the Act, 15 U.S.C. 2003(d).

(5) *Manufacturer* has the meaning given it in section 501(9) of the Act, 15 U.S.C. 2001(9).

(6) *Model type* has the meaning given it in section 501(11) of the Act, 15 U.S.C. 2001(11).

(b) *Applicability.* This section applies only to information provided to or obtained by EPA under Title V, Part A of the Act, 15 U.S.C. 2001 through 2012. Information will be considered to have been provided or obtained under Title V, Part A of the Act if it was provided in response to a request from EPA made for any purpose stated in Title V, Part A, or if its submission could have been required under Title V, Part A, regardless of whether Title V, Part A was cited as the authority for any request for information or whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207 and §§ 2.209 through 2.216 apply without change to information to which this section applies.

(d) [*Reserved*]

(e) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies, except that information that is fuel economy data is not eligible for confidential treatment.

(f) [*Reserved*]

(g) *Disclosure of information relevant to a proceeding.*

(1) Under section 505(d)(1) of the Act, any information to which this section applies may be released by EPA because of the relevance of the information to a proceeding under Title V, Part A of the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Release of information to which this section applies because of its relevance to a proceeding shall be made only in accordance with this paragraph (g).

(2) The provisions of § 2.301(g)(2), (g)(3), and (g)(4) must be followed when making disclosures pursuant to paragraph (g) of this section.

PART 57—[AMENDED]

5. The authority citation for part 57 continues to read as follows:

Authority: Secs. 110, 114, 119, 301, Clean Air Act as amended (42 U.S.C. 7410, 7414, 7419, and 7601); sec. 406 of Pub. L. 95–95.

6. Section 57.203 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 57.203 Contents of the application.

(a) Claim of confidentiality. The smelter owner may make a business confidentiality claim covering all or part of the information in the NSO application in accordance with 40 CFR part 2, subpart B. * * *

* * * * *

7. Appendix A of part 57 is amended by revising the second sentence of instruction 1.3 to read as follows:

Appendix A to Part 57—Primary Nonferrous Smelter Order (NSO) Application

* * * * *

1.3 *Confidentiality.* * * * Agency regulations concerning claims of confidentiality of business information are contained in 40 CFR part 2, subpart B. * * *

* * * * *

PART 85—[AMENDED]

8. The authority citation for part 85 continues to read as follows:

Authority: Secs. 202, 208, and 301(a), Clean Air Act, as amended (42 U.S.C. 7521, 7542 and 7601(a)).

9. Section 85.1712 is amended by revising paragraph (e) to read as follows:

§ 85.1712 Treatment of confidential information.

* * * * *

(e) Information provided without a claim of confidentiality at the time of submission may be made available to the public by EPA without further notice to the submitter.

10. Section 85.1808 is amended by revising paragraph (e) to read as follows:

§ 85.1808 Treatment of confidential information.

* * * * *

(e) Information provided without a claim of confidentiality at the time of submission may be made available to the public by EPA without further notice to the submitter.

11. Section 85.1909 is amended by revising paragraph (e) to read as follows:

§ 85.1909 Treatment of confidential information.

* * * * *

(e) Information provided without a claim of confidentiality at the time of submission may be made available to the public by EPA without further notice to the submitter.

12. Section 85.2123 is amended by revising paragraph (e) to read as follows:

§ 85.2123 Treatment of confidential information.

* * * * *

(e) Information provided without a claim of confidentiality at the time of submission may be made available to the public by EPA without further notice to the submitter.

PART 86—[AMENDED]

13. The authority citation for part 86 continues to read as follows:

Authority: Secs. 202, 203, 206, 207, 208, 215, 301(a), Clean Air Act, as amended (42 U.S.C. 7521, 7522, 7524, 7525, 7541, 7549, 7550, 7552, and 7601(a)), unless otherwise noted.

14. Section 86.615–84 is amended by revising paragraph (e) to read as follows:

§ 86.615–84 Treatment of confidential information.

* * * * *

(e) Information provided without a claim of confidentiality at the time of submission may be made available to the public by EPA without further notice to the submitter.

15. Section 86.1015 is amended by revising paragraph (e) to read as follows:

§ 86.1015 Treatment of confidential information.

* * * * *

(e) Information provided without a claim of confidentiality at the time of submission may be made available to the public by EPA without further notice to the submitter.

16. Section 86.1116–87 is amended by revising paragraph (e) to read as follows:

§ 86.1116–87 Treatment of confidential information.

* * * * *

(e) Information provided without a claim of confidentiality at the time of submission may be made available to the public by EPA without further notice to the submitter.

PART 122—[AMENDED]

17. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 *et seq.*

18. Section 122.7 is amended by revising paragraph (a) to read as follows:

§ 122.7 Confidentiality of information.

(a) In accordance with 40 CFR part 2, any information submitted to EPA pursuant to these regulations may be claimed as confidential by the submitter. Any such claim must be asserted at the time of submission in the manner prescribed in the application form or instructions or, in the case of

other submission, by stamping the words "confidential business information" on each page containing such information. If no claim is made at the time of submission, EPA may make the information available to the public without further notice. If a claim covering the information is received after the information itself is received, EPA will make such efforts as are administratively practicable to associate the late claim with copies of the previously-submitted information in EPA files. However, EPA cannot assure that such efforts will be effective, in light of the possibility of prior disclosure or widespread prior dissemination of the information. If a claim is asserted, the information will be treated in accordance with the procedures in 40 CFR part 2 (Public Information).

* * * * *

PART 123—[AMENDED]

19. The authority citation for part 123 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

20. Section 123.41 is amended by revising paragraph (a) to read as follows:

§ 123.41 Sharing of information.

(a) Any information obtained or used in the administration of a State program shall be available to EPA upon request without restriction. If the information has been submitted to the State under a claim of confidentiality, the State must submit that claim to EPA when providing information under this section. Any information obtained from a State and subject to a claim of confidentiality will be treated in accordance with the regulations in 40 CFR part 2. If EPA obtains from a State information that is not claimed to be confidential, EPA may make that information available to the public without further notice. If a claim covering the information is received after the information itself is received, EPA will make such efforts as are administratively practicable to associate the late claim with copies of the previously-submitted information in EPA files. However, EPA cannot assure that such efforts will be effective, in light of the possibility of prior disclosure or widespread prior dissemination of the information.

* * * * *

21. Section 123.42 is amended by revising the first sentence of the introductory text to read as follows:

§ 123.42 Receipt and use of Federal information.

Upon approving a State permit program, EPA shall send to the State agency administering the permit program, subject to the conditions in 40 CFR part 2, any relevant information which was collected by EPA. * * *

* * * * *

PART 145—[AMENDED]

22. The authority citation for part 145 continues to read as follows:

Authority: 42 U.S.C. 300f *et seq.*

23. Section 145.14 is amended by revising paragraph (a) to read as follows:

§ 145.14 Sharing of information.

(a) Any information obtained or used in the administration of a State program shall be available to EPA upon request without restriction. If the information has been submitted to the State under a claim of confidentiality, the State must submit that claim to EPA when providing information under this section. Any information obtained from a State and subject to a claim of confidentiality will be treated in accordance with the regulations in 40 CFR part 2. If EPA obtains from a State information that is not claimed to be confidential, EPA may make that information available to the public without further notice. If a claim covering the information is received after the information itself is received, EPA will make such efforts as are administratively practicable to associate the late claim with copies of the previously-submitted information in EPA files. However, EPA cannot assure that such efforts will be effective, in light of the possibility of prior disclosure or widespread prior dissemination of the information.

* * * * *

PART 233—[AMENDED]

24. The authority citation for part 233 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

25. Section 233.3 is amended by revising paragraph (a) to read as follows:

§ 233.3 Confidentiality of information.

(a) Any information submitted to EPA pursuant to these regulations may be claimed as confidential by the submitter at the time of submittal. Information so claimed will be treated in accordance with the procedures in 40 CFR part 2.

* * * * *

PART 260—[AMENDED]

26. The authority citation for part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974.

27. Section 260.2 is amended by revising paragraph (b) to read as follows:

§ 260.2 Availability of information; confidentiality of information.

* * * * *

(b) Any person who submits information to EPA in accordance with parts 260 through 266 and 268 of this chapter may assert a claim of business confidentiality covering part or all of that information by following the procedures set forth in § 2.203(b) of this chapter. Information covered by such a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in part 2, subpart B, of this chapter. However, if no such claim accompanies the information when it is received by EPA, it may be made available to the public without further notice to the person submitting it. If a claim covering the information is received after the information itself is received, EPA will make such efforts as are administratively practicable to associate the late claim with copies of the previously-submitted information in EPA files. However, EPA cannot assure that such efforts will be effective, in light of the possibility of prior disclosure or widespread prior dissemination of the information. Pursuant to § 2.305(f) of this chapter, information required by § 262.53(a) which is submitted in notification of intent to export a hazardous waste will be provided to the Department of State and the appropriate authorities in a receiving country regardless of any claims of confidentiality.

PART 270—[AMENDED]

28. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

29. Section 270.12 is amended by revising paragraph (a) to read as follows:

§ 270.12 Confidentiality of information.

(a) In accordance with 40 CFR part 2, any information submitted to EPA pursuant to these regulations may be claimed as confidential by the submitter. Any such claim must be asserted at the time of submission in the manner prescribed in the application form or instructions or, in the case of other submissions, by stamping the words "confidential business

information" on each page containing such information. If no claim is made at the time of submission, EPA may make the information available to the public without further notice. If a claim covering the information is received after the information itself is received, EPA will make such efforts as are administratively practicable to associate the late claim with copies of the previously-submitted information in EPA files. However, EPA cannot assure that such efforts will be effective, in light of the possibility of prior disclosure or widespread prior dissemination of the information. If a claim is asserted, the information will be treated in accordance with the procedures in 40 CFR part 2 (Public Information).

* * * * *

PART 271—[AMENDED]

30. The authority citation for part 271 continues to read as follows:

Authority: 42 U.S.C. 9602; 33 U.S.C. 1321 and 1361.

31. Section 271.17 is amended by revising paragraph (a) to read as follows:

§ 271.17 Sharing of information.

(a) Any information obtained or used in the administration of a State program shall be available to EPA upon request without restriction. If the information has been submitted to the State under a claim of confidentiality, the State must submit that claim to EPA when providing information under this subpart. Any information obtained from a State and subject to a claim of confidentiality will be treated in accordance with the regulations in 40 CFR part 2. If EPA obtains from a State information that is not claimed to be confidential, EPA may make that information available to the public without further notice. If a claim covering the information is received after the information itself is received, EPA will make such efforts as are administratively practicable to associate the late claim with copies of the previously-submitted information in EPA files. However, EPA cannot assure that such efforts will be effective, in light of the possibility of prior disclosure or widespread prior dissemination of the information.

* * * * *

32. Section 271.132 is amended by revising paragraph (a) to read as follows:

§ 271.132 Sharing of information.

(a) Any information obtained or used in the administration of a State program shall be available to EPA upon request without restriction. If the information has been submitted to the State under a claim of confidentiality, the State must submit that claim to EPA when providing information under this subpart. Any information obtained from a State and subject to a claim of confidentiality will be treated in accordance with the regulations in 40 CFR part 2. If EPA obtains from a State information that is not claimed to be confidential, EPA may make that information available to the public without further notice. If a claim covering the information is received after the information itself is received, EPA will make such efforts as are administratively practicable to associate the late claim with copies of the previously-submitted information in EPA files. However, EPA cannot assure that such efforts will be effective, in light of the possibility of prior disclosure or widespread prior dissemination of the information.

* * * * *

PART 281—[AMENDED]

33. The authority citation for part 281 continues to read as follows:

Authority: Sections 2002, 9004, 9005, 9006 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6912, 6991 (c), (d), (e).

34. Section 281.43 is amended by revising paragraph (a)(1) to read as follows:

§ 281.43 Sharing of information.

(a) * * *

(1) Any information submitted to the State under a claim of confidentiality. The State must submit that claim to EPA when providing such information. If a claim covering the information is received after the information itself is received, EPA will make such efforts as are administratively practicable to associate the late claim with copies of the previously-submitted information in EPA files. However, EPA cannot assure that such efforts will be effective, in light of the possibility of prior disclosure or widespread prior dissemination of the information. Any information obtained from a State and subject to a claim of confidentiality will be treated in accordance with federal regulations in 40 CFR part 2; and

* * * * *

PART 350—[AMENDED]

35. The authority citation for part 350 continues to read as follows:

Authority: 42 U.S.C. 11042, 11043 and 11048 Pub. L. 99–499, 100 Stat. 1747.

36. Section 350.23 is amended by revising paragraph (b)(3) and removing paragraph (b)(4) to read as follows:

§ 350.23 Disclosure to authorized representatives.

* * * * *

(b) * * *

(3) No information shall be disclosed under this § 350.23(b) until each affected submitter has been furnished notice (by letter, **Federal Register**, or other means) of the contemplated disclosure by the EPA program office and has been afforded a period found reasonable by that office (not less than 5 working days) to submit its comments. Such notice shall include a description of the information to be disclosed, the identity of the contractor, subcontractor or grantee, and the purposes to be served by the disclosure. The office preparing the notice must respond in writing to all comments submitted by affected businesses.

PART 403—[AMENDED]

37. The authority citation for part 403 continues to read as follows:

Authority: Sec. 54(c)(2) of the Clean Water Act of 1977 (Pub. L. 95–217), sections 204(b)(1)(C), 208(b)(2)(C)(iii), 301(b)(1)(A)(ii), 301(b)(2)(A)(ii), 301(b)(2)(C), 301(h)(5), 301(i)(2), 304(e), 304(g), 307, 308, 309, 402(b), 405 and 501(a) of the Federal Water Pollution Control Act (Pub. L. 92–500) as amended by the Clean Water Act of 1977 and the Water Quality Act of 1987 (Pub. L. 100–4).

38. Section 403.14 is amended by revising paragraph (a) to read as follows:

§ 403.14 Confidentiality.

(a) *EPA Authorities.* In accordance with 40 CFR part 2, any information submitted to EPA pursuant to these regulations may be claimed as confidential by the submitter. Any such claim must be asserted at the time of submission in the manner prescribed in the application form or instructions, or, in the case of other submission, by stamping the words "confidential business information" on each page containing such information. If no claim is made at the time of submission, EPA may make the information available to the public without further notice. If a claim covering the information is received after the information itself is received, EPA will make such efforts as are administratively practicable to associate the late claim with copies of the previously-submitted information in EPA files. However, EPA cannot assure that such efforts will be effective, in light of the possibility of prior disclosure or widespread prior dissemination of the information. If a

claim is asserted, the information will be treated in accordance with the procedures in 40 CFR part 2 (Public Information).

* * * * *

PART 704—[AMENDED]

39. The authority citation for part 704 is revised to read as follows:

Authority: 15 U.S.C. 2607(a) and 2613.

40. Section 704.7 is amended by revising paragraphs (a) and (d) introductory text to read as follows:

§ 704.7 Confidential business information claims.

(a) Any person submitting a notice under this rule may assert a business confidentiality claim covering all or any part of the information. A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all business confidentiality claims. Any information covered by a claim will be disclosed by EPA only to the extent and by means of the procedures set forth in part 2 of this chapter.

* * * * *

(d) In submitting a claim of confidentiality, a senior management official, as defined in 40 CFR 2.306(a)(7), attests to the truth of the following four statements concerning all the information claimed confidential:

* * * * *

41. Section 704.219 is amended by adding paragraph (c)(2) and revising paragraph (d) to read as follows:

§ 704.219 Confidential business information claims.

* * * * *

(c) * * *

(2) A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all reports containing confidentiality claims.

(d) Submitters must substantiate all claims of confidentiality at the time the submitter asserts the claim (i.e., when the reporting form is submitted). A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all substantiations of claims of confidentiality. Failure to provide substantiation of a claim at the time the submitter submits the reporting form will result in a waiver of the confidentiality claim, and the information may be disclosed to the public without further notice to the submitter.

* * * * *

PART 707—[AMENDED]

42. The authority citation for part 707 is revised to read as follows:

Authority: 15 U.S.C. 2611(b), 2612 and 2613.

43. Section 707.75 is amended by revising paragraph (a) to read as follows:

§ 707.75 Confidentiality.

(a) A person may assert a claim of confidentiality for any information which is submitted to EPA in a notice. A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all claims of confidentiality.

* * * * *

PART 710—[AMENDED]

44. The authority citation for part 710 is revised to read as follows:

Authority: 15 U.S.C. 2607(a) and 2613.

45. Section 710.7 is amended by revising paragraph (b) to read as follows:

§ 710.7 Confidentiality.

* * * * *

(b) Any claims of confidentiality must accompany the information at the time it is submitted to EPA. The claims must appear on the form on which the information is submitted to EPA and in the manner prescribed on the form. In addition, any claims of confidentiality must be substantiated at the time the information is submitted to EPA in the manner specified in the form instructions. A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all claims of confidentiality and substantiations.

* * * * *

46. Section 710.38 is amended by revising paragraph (a) and the introductory text of paragraph (c)(1) to read as follows:

§ 710.38 Confidentiality.

(a) Any person submitting information under this subpart may assert a business confidentiality claim for the information. A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all business confidentiality claims. The procedures for asserting confidentiality claims are described in the instruction booklet identified in § 710.39. Information claimed as confidential in accordance with this section and those instructions will be treated and disclosed in accordance with the procedures in part 2 of this chapter.

* * * * *

(c) * * *

(1) The person must submit with the report detailed written answers to the following questions signed and dated by a senior management official, as defined in 40 CFR 2.306(a)(7).

* * * * *

PART 712—[AMENDED]

47. The authority citation for part 712 is revised to read as follows:

Authority: 15 U.S.C. 2607(a) and 2613.

48. Section 712.15 is amended by revising paragraph (b) to read as follows:

§ 712.15 Confidentiality.

* * * * *

(b) A senior management official, as defined in 40 CFR 2.306(a)(7), must certify to the validity of the claim of confidentiality asserted for information reported under this part, as specified on the reporting form.

* * * * *

PART 716—[AMENDED]

49. The authority citation for part 716 is revised to read as follows:

Authority: 15 U.S.C. 2607(d) and 2613.

50. Section 716.55 is amended by adding paragraphs (a)(5) and (a)(6) to read as follows:

§ 716.55 Confidentiality claims.

(a) * * *

(5) Any respondent who wishes to assert a claim of confidentiality for chemical identity must substantiate such claim in accordance with 40 CFR 2.306(d)(2). A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all substantiations. If no claim of confidentiality for chemical identity accompanies the submission or if the substantiation required under this paragraph (a)(5) is not submitted at the time of assertion of the claim, EPA will deem the claim for chemical identity waived and may make the identity public without further notice to the submitter.

(6) A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all submissions containing confidentiality claims.

* * * * *

PART 717—[AMENDED]

51. The authority citation for part 717 is revised to read as follows:

Authority: 15 U.S.C. 2607(c) and 2613.

52. Section 717.19 is amended by adding paragraphs (c)(5) and (c)(6) to read as follows:

§ 717.19 Confidentiality.

* * * * *

(c) * * *

(5) Any respondent who wishes to assert a claim of confidentiality for chemical identity must substantiate such claim in accordance with 40

CFR2.306(d)(2). A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all substantiations. If no claim of confidentiality for chemical identity accompanies the submission or if the substantiation required under this subparagraph is not submitted at the time of assertion of the claim, EPA will deem the claim for chemical identity waived and may make the identity public without further notice to the submitter.

(6) A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all submissions containing confidentiality claims.

PART 720—[AMENDED]

53. The authority citation for part 720 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607 and 2613.

54. Section 720.80 is amended by adding paragraph (b)(3) to read as follows:

§ 720.80 General provisions.

* * * * *

(b) * * *

(3) A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all notice forms containing any claims of confidentiality.

* * * * *

55. Section 720.85 is amended by revising paragraph (b)(3)(iv), introductory text, to read as follows:

§ 720.85 Chemical identity.

* * * * *

(b) * * *

(3) * * *

(iv) Provide a detailed written substantiation of the claim, signed by a senior management official, as defined in 40 CFR 2.306(a)(7), by answering the following questions:

* * * * *

56. Section 720.90 is amended by adding a sentence after the first sentence of paragraph (b)(2) to read as follows:

§ 720.90 Data from health and safety studies.

* * * * *

(b) * * *

(2) *Claims applicable to period after commencement of manufacture or import for commercial purposes.* * * * A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign such reassertions and substantiations of claims of confidentiality for chemical identity.

* * * * *

PART 723—[AMENDED]

57. The authority citation for part 723 is revised to read as follows:

Authority: 15 U.S.C. 2604 and 2613.

58. Section 723.50 is amended by revising paragraph (k)(1) to read as follows:

§ 723.50 Chemical substances manufactured in quantities of 1,000 kilograms or less per year.

* * * * *

(k) *Confidentiality.* (1) If the manufacturer submits to EPA under this section information which it claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with "CONFIDENTIAL" or some other appropriate designation. A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all business confidentiality claims. Any information so identified will be treated in accordance with the procedures in part 2 of this chapter. Any information not claimed as confidential at the time of submission may be made available to the public without further notice.

* * * * *

59. Section 723.175 is amended by revising paragraph (k) to read as follows:

§ 723.175 Chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles.

* * * * *

(k) *Confidentiality.* If the manufacturer submits to EPA under paragraph (i) or (j) of this section information which it claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with "CONFIDENTIAL" or some other appropriate designation. A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all business confidentiality claims. Any information so identified will be treated in accordance with the procedures in part 2 of this chapter. Any information not claimed as confidential at the time of submission will be made available to the public without further notice to the submitter.

* * * * *

PART 750—[AMENDED]

60. The authority citation for part 750 is revised to read as follows:

Authority: 15 U.S.C. 2605 and 2613.

61. Section 750.16 is revised to read as follows:

§ 750.16 Confidentiality.

The Agency encourages the submission of nonconfidential information by petitioners and commenters. The Agency does not wish to have unnecessary restrictions on access to the rulemaking record. However, if a petitioner or commenter believes that he can only state his position through the use of information claimed to be confidential, he may submit it. Such information must be separately submitted for the rulemaking record and marked "confidential" by the submitter. A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all business confidentiality claims. For information claimed to be confidential, the Agency will list only the date and the name and address of the petitioner or commenter in the public file, noting that the petitioner or commenter has requested confidential treatment. The information claimed to be confidential will be placed in a confidential file. A petitioner must also file a nonconfidential petition with a nonconfidential summary of the confidential information to be placed in the public file. Similarly, a commenter must supply a nonconfidential summary of the information claimed to be confidential to be placed in the public file. Any information not marked as confidential will be placed in the public file. Information marked as confidential will be treated in accordance with the procedures in part 2, subpart B of this chapter.

62. Section 750.36 is revised to read as follows:

§ 750.36 Confidentiality.

EPA encourages the submission of non-confidential information by petitioners and commenters. EPA does not wish to have unnecessary restrictions on access to the rulemaking record. However, if a petitioner or commenter believes that he can only state his position through the use of information claimed to be confidential, he may submit it. Such information must be separately submitted for the rulemaking record and marked "confidential" by the submitter. A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all business confidentiality claims. For information claimed to be confidential, EPA will list only the date and the name and address of the petitioner or commenter in the public file, noting that the petitioner or commenter has requested confidential treatment. The

information claimed to be confidential will be placed in a confidential file. A petitioner must also file a non-confidential petition with a non-confidential summary of the confidential information to be placed in the public file. Similarly, a commenter must supply a non-confidential summary of the information claimed to be confidential to be placed in the public file. Any information not marked as confidential will be placed in the public file. Information marked confidential will be treated in accordance with the procedures in part 2, subpart B of this chapter.

PART 790—[AMENDED]

63. The authority citation for part 790 is revised to read as follows:

Authority: 15 U.S.C. 2603 and 2613.

64. Section 790.7 is amended by revising paragraphs (a), (b) and (c), introductory text, to read as follows:

§ 790.7 Confidentiality.

(a) Any person subject to a consent agreement or test rule under section 4 of the Act may assert a claim of confidentiality claim for certain information submitted to EPA in response to the consent agreement or test rule. A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all business confidentiality claims. Any information claimed as confidential will be treated in accordance with the procedures in part 2 of this chapter and section 14 of the Act. Failure to assert a claim of confidentiality at the time the information is submitted will result in the information being made available to the public without further notice to the submitter.

(b) A claim of confidentiality must be asserted by circling or otherwise marking the specific information claimed as confidential and designating it with the words "confidential business information," "trade secret," or another appropriate phrase indicating its confidential character. Any respondent who wishes to assert a claim of confidentiality for chemical identity must substantiate such claim in accordance with 40 CFR 2.306(d)(2). A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all substantiations. If no claim of confidentiality for chemical identity accompanies the document submission or if the substantiation required under this paragraph (b) is not submitted at the time of assertion of the claim, EPA will deem the claim for chemical identity waived and may make the identity public without further notice to the submitter.

(c) If a person asserts a claim of confidentiality for study plan information described in § 790.50(c)(1)(iii)(D), (iv), (v), and (vi) and § 790.62(b)(6), (7), (8), (9) and (10), the person must provide a detailed written substantiation of the claim by answering the questions in this paragraph. A senior management official, as defined in 40 CFR 2.306(a)(7), shall sign all substantiations. Failure to provide written substantiation at the time the study plan information is submitted will be considered a waiver of the claim of confidentiality, and the study plan information will be disclosed to the public without further notice.

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Wednesday
November 23, 1994

Part IV

Environmental Protection Agency

Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA); Proposed Policy; Notice

40 CFR Parts 152, 174, and 180

Proposed Exemptions from the Requirement of a Tolerance for Plant-Pesticides and Nucleic Acids and Viral Coat Proteins Produced in Plants Under FFDCA, and Plant-Pesticides Subject to FIFRA; Proposed Rules

ENVIRONMENTAL PROTECTION AGENCY

[OPP–300370; FRL–4755–2]

RIN 2070–AC02

Proposed Policy; Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Statement of policy.

SUMMARY: This notice describes how EPA proposes to address pesticidal substances produced by plants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Substances that plants produce to protect themselves against pests and disease are pesticides under the definition of FIFRA section 2, (i.e., if they are ". . .intended for preventing, destroying, repelling, or mitigating any pest. . .") regardless of whether the pesticidal capabilities evolved in the plants or were introduced by breeding or through the techniques of modern biotechnology. These substances, along with the genetic material necessary to produce them, are designated "plant-pesticides." This policy statement: (1) Clarifies the regulatory status under FIFRA and FFDCA of plants and plant-pesticides; (2) stipulates that EPA's regulatory attention will focus on plant-pesticides rather than on plants per se; (3) describes the criteria EPA is proposing to use in determining which plant-pesticides will be subject to regulation and which will be exempt; and (4) describes EPA's proposed procedures and information needs for the regulation of testing and commercial sale and distribution of plant-pesticides.

DATES: Comments identified by the docket control number [OPP–300370] must be received on or before January 23, 1995.

ADDRESSES: Submit written comments by mail to: Program Resources Section, Public Response and Program Resources Branch, Field Operations Division (7506C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the Virginia address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Bernice Slutsky, Science and Policy Staff, Office of Prevention, Pesticides and Toxic Substances (7101), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. E–627, 401 M St., SW., Washington, DC, (202–260–6900).

SUPPLEMENTARY INFORMATION:

I. Introduction and History of the Policy

A. Introduction

EPA has received numerous inquiries concerning the regulation of plants that have been modified to produce pesticidal substances, particularly since modern biotechnology has provided the means of introducing novel pesticidal substances into plants. These inquiries have come from industry, public interest groups, and other government agencies. The principal focus of these inquiries has been requests for clarification of the regulatory status, under FIFRA (7 U.S.C. 136 *et seq.*) and FFDCA (21 U.S.C. 321 *et seq.*), of plants and the pesticidal substances that they produce.

Most plant varieties have the ability to resist pests and disease. The mechanisms of resistance can be varied, including structural characteristics of the plant, the production of general metabolites that have toxic properties, or the production of specific toxic substances in response to pest attack. A plant can be completely immune to a pest or can be partially resistant.

Plant varieties with a greater ability to withstand pests have traditionally been bred from progenitor plants that have high levels of resistance to the target pest. It is now also possible to introduce into plants mechanisms of pest and disease resistance that are not found in the plant kingdom. For example, plants can be modified to express toxins from invertebrates and microorganisms. These toxins can confer plant resistance to insect attack and disease. Such pesticidal substances can be diverse and can potentially originate from any taxonomic kingdom.

There are a number of types of substances produced in plants that enable plants to resist pest attack and disease. These substances include both those pesticidal substances that would be considered normally a component of a plant and those that would be considered new to a plant. Examples of plant-pesticides that would be considered normally a component of a plant are phytoalexins (plant-produced substances that act against phytopathogenic microorganisms). An example of a plant-pesticide that would not be considered normally a component of a plant is the insecticidal delta endotoxin that is produced in the bacterium, *Bacillus thuringiensis*.

This policy statement clarifies the regulatory status, under FIFRA and FFDCA, of plants that act as biological control agents (and thus can be considered pesticides) and the plant-pesticides produced by plants. In doing so, it clarifies that plants continue to be exempt, and it defines the categories of plant-pesticides that would be regulated by EPA under FIFRA and FFDCA. This document outlines EPA's proposed procedures to assess plant-pesticides at different stages of testing and at sale or distribution. It also describes the information that EPA would need to evaluate those plant-pesticides that the Agency is proposing would be subject to EPA regulation under FIFRA and FFDCA.

This policy statement is based upon the Agency's current knowledge of new plant varieties under development in agricultural research, particularly those developed through the new techniques of biotechnology. Accordingly, while this policy statement would apply to all plant-pesticides produced in plants (including bryophytes such as mosses, seedless vascular plants such as ferns, gymnosperms such as conifers, and angiosperms such as most major crop plants), it concentrates primarily on proteinaceous plant-pesticides produced in new varieties of terrestrial crops.

In developing its policy on plant-pesticides under FIFRA and FFDCA, the Agency considered how the two statutes authorize EPA to regulate pesticides and pesticide residues, the differences in statutory criteria imposed by each statute, and how the statutes complement each other. Under the approach articulated in this policy statement, the Agency believes that most plant-pesticides would not require regulation under FIFRA. However, the Agency believes some type of oversight is appropriate for plant-pesticides that are new to the plant and have a toxic mechanism of action (see Unit IV.B. of

this document). Similarly under FFDCA, the Agency believes that most plant-pesticides should be exempt from the requirement of a tolerance. However, the Agency believes that EPA review should take place for certain plant-pesticides that are used in food/feed (see Unit IV.C. of this document).

This statement of policy is one of several documents published in today's **Federal Register** that address EPA's regulation of plant-pesticides. The other documents are: (1) a proposed regulatory amendment that would describe categories of plant-pesticides that are subject to or exempt from regulation under FIFRA and clarifies the status of plants that produce plant-pesticides ("Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Policy"); (2) a proposed exemption from the requirement of a tolerance under FFDCA for categories of plant-pesticides that do not result in significantly different dietary exposures ("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act"); (3) a proposed exemption from the requirement of a tolerance under FFDCA for viral coat proteins ("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants"); and (4) a proposed exemption from the requirement of a tolerance under FFDCA for nucleic acids, including deoxyribonucleic and ribonucleic acids ("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants").

B. History

Since 1987, EPA has sponsored, or co-sponsored with other Federal agencies, three conferences that discussed whether transgenic plants (plant varieties developed through new biotechnology methodologies) producing pesticidal substances pose potential risks and the nature of those risks. In addition, EPA has requested advice on how best to address plant-pesticides from two scientific advisory committees at three meetings. On December 18, 1992, a Subpanel of the FIFRA Scientific Advisory Panel (SAP) was convened to review a draft proposed policy statement and to answer a series of scientific questions concerned primarily with EPA's proposed approach for plant-pesticides under FIFRA. On July 13, 1993, a Subcommittee of the EPA Biotechnology Science Advisory Committee (BSAC) was convened to address a series of scientific questions concerned primarily with EPA's proposed approach for plant-pesticides under FFDCA. On January 21, 1994, a joint SAP/BSAC Subpanel was convened to address a series of scientific questions concerned with the scope of regulation under FIFRA and FFDCA and guidance for data needs for the evaluation of plant-pesticides. For more detailed discussion of the reports from the three advisory committee meetings, refer to Unit VIII. of this document.

II. Summary of Proposed Policy Under FIFRA and FFDCA

A. Introduction

On June 2, 1982, EPA promulgated a final regulation under FIFRA section 25(b) that exempted all biological control agents, except for certain microorganisms, from the requirements of FIFRA (47 FR 23928; see 40 CFR 152.20). EPA defines the term "biological control agent" as "any living organism applied to or introduced into the environment that is intended to function as a pesticide against another organism declared to be a pest by the Administrator" (40 CFR 152.3). The exemption of biological control agents was promulgated because EPA found that the risks posed by biological control agents other than microorganisms were adequately addressed by other Federal agencies such as the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) and the U.S. Department of the Interior. Although plants used as biological control agents were not specifically addressed in the June 2, 1982, **Federal Register** notice, they have been excluded from regulation under FIFRA through this exemption. EPA continues to believe that plants used as biological control agents are adequately regulated by other Federal agencies. However, EPA believes that the status of pesticidal substances produced in plants (i.e., plant-pesticides) requires regulatory clarification.

Although plants used as biological control agents were excluded from FIFRA regulation under 40 CFR 152.20, substances that are extracted from plants and used as pesticides are not similarly excluded. For example, chrysanthemums produce pyrethrum, a substance that has insecticidal activity. The chrysanthemum plants that produce pyrethrum have been exempted from regulation when used as biological control agents (i.e., living chrysanthemums), but pyrethrum itself, as the pesticide substance, has not been exempted when extracted from chrysanthemums and applied to other plants as an insecticide.

This distinction is reasonable in light of the potential for increased and unique exposures due to large-scale application of extracted pyrethrum to plants that do not naturally produce it. The use of extracted pyrethrum as an insecticide can involve exposure to the pesticide over large acreages, whereas the exposure associated with pyrethrum in living chrysanthemum plants would not be expected to reach such proportions. In addition, application of pyrethrum beyond the environment in which it is normally produced (i.e., beyond the living chrysanthemum plant) could result in new or unique exposures of nontarget organisms, including humans.

Although it has been EPA's policy under FIFRA to regulate pesticidal substances extracted from plants, EPA has not, thus far, clearly stated its policies for regulation of pesticidal substances that are produced in living plants but not extracted from the plants (plant-pesticides). This policy statement, and the companion document published elsewhere in today's issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule," is designed to provide such clarification for pesticidal substances that have evolved in plants, for pesticidal substances introduced into plants by breeding, and for pesticidal substances introduced into plants through biotechnology.

Similarly under FFDCA, EPA has regulated substances that are extracted from plants and used as pesticides on food or feed. For example, a tolerance has been set for pyrethrum that is extracted from plants and applied to food or feed. However, the Agency has not clearly explained how pesticidal substances produced in plants (plant-pesticides) would be regulated under FFDCA. For example, if a food plant could be modified, for pesticidal purposes, to produce pyrethrum, EPA has not, thus far, explained how this pyrethrum would be regulated under FFDCA.

It is the intent of this policy statement to give guidance as to the types of plant-pesticides that would be evaluated by the Agency under FFDCA. The considerations used to determine whether EPA review would be required will be set forth in this policy statement and the companion **Federal Register** documents ("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act"; "Plant-

pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants"; "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants").

B. Proposed Regulatory Scheme

In order to establish an effective regulatory scheme appropriate to plant-pesticides, EPA proposes to take the following actions under FIFRA and FFDCA. The Agency makes clear that the substances plants produce to protect themselves against pests and disease are pesticides under the FIFRA section 2 definition of "pesticide," i.e., if they are ". . .intended for preventing, destroying, repelling or mitigating any pest." Pesticidal substances that are produced in the living plant along with the genetic material necessary for the production of those substances are designated by EPA as plant-pesticides (Unit IV.B. of this document). The definition of pesticide under FIFRA section 2 also includes "plant regulators." The Agency provides criteria for determining when a substance produced in a living plant but not extracted from the plant is a plant regulator (Unit IV.D. of this document), and the rationales EPA employed in developing these criteria.

EPA indicates that it proposes to focus its regulatory attention on the plant-pesticide and not on the plant per se. The Agency defines the categories of plant-pesticides that it proposes to regulate under FIFRA and FFDCA. In general, the Agency would regulate, under FIFRA, those plant-pesticides that have the greatest potential for new environmental exposures and adverse effects to nontarget organisms. To do this, EPA proposes to exempt from FIFRA requirements, certain classes of plant-pesticides based upon the source from which the plant-pesticide is derived and the mechanism of action of the pesticidal substance. Also contained in the proposed FIFRA exemption are coat proteins from plant viruses. Plant-pesticides that do not fall within these exemptions would be subject to FIFRA regulation. In a proposal published elsewhere in todays issue of the **Federal Register** a new part in 40 CFR, part 174, would establish the scope of regulation for plant-pesticides under FIFRA ("Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule").

Under FFDCA, the Agency would regulate those plant-pesticides that have the greatest potential for new dietary exposures. To establish the FFDCA scope of coverage, EPA proposes three exemptions from the requirements of a tolerance for three categories of plant-pesticides: (1) Certain plant-pesticides commonly found in food; (2) coat proteins from plant viruses; and (3) nucleic acids (see documents published elsewhere in todays issue of the **Federal Register** entitled, "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act"; "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants"; and "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants"). Plant-pesticides that do not fall within these exemptions would be subject to the FFDCA tolerance requirements.

Recognizing the unique characteristics of plant-pesticides, the Agency is proposing to establish a new part 174, in 40 CFR under FIFRA for plant-pesticides ("Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule"). In the future EPA will propose, under part 174, procedural requirements for plant pesticides.

In this proposed policy statement, EPA provides information on how manufacturers, importers, and distributors of plant-pesticides subject to FIFRA and FFDCA requirements should interact with the Agency. This guidance contains (1) Information on when and how manufacturers should first consult with the Agency; (2) a set of "points to consider" to assist manufacturers in developing data for review; (3) descriptions of proposed Agency procedures for Experimental Use Permits (EUPs) and registration; and (4) descriptions of EPA's interaction with other agencies.

III. Statutory and Regulatory Background

This policy was developed under the authority of FIFRA, as amended (7 U.S.C. 136 *et seq.*) and FFDCA (21 U.S.C. 321 *et seq.*). Under FIFRA, a pesticide may not be sold or distributed in the United States unless it is registered, or has been exempted from regulation. Under FFDCA, EPA has the authority to set tolerances or establish an exemption from the requirement of a tolerance for pesticide residues in or on raw agricultural commodities and to establish food additive regulations for pesticide residues in or on processed foods.

A. FIFRA

FIFRA section 2(u) defines "pesticide" as: "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliator, or desiccant. . . ."

FIFRA section 3 provides that no person may distribute or sell in the United States any pesticide that is not registered under the Act. Before a product may be registered as a pesticide under FIFRA, it must be shown that when used in accordance with widespread and commonly recognized practice, it will not generally cause "unreasonable adverse effects on the environment." FIFRA section 2(bb) defines the term "unreasonable adverse effects on the environment" as any unreasonable risk to "man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Thus, FIFRA involves a balancing of the risks presented by the use of the pesticide against the benefits associated with the use of that pesticide.

In addition to the requirement for a registration, FIFRA authorizes EPA to issue EUPs under section 5 and to otherwise regulate the use of unregistered pesticides under FIFRA section 3(a). Section 5 of FIFRA and 40 CFR part 172 provide for issuance by the Agency of Experimental Use Permits (EUP's) for the testing of new, unregistered pesticides or registered pesticides being tested for new uses in which the purpose is only to determine its value for pesticide purposes or to determine its toxicity or other properties. Such permits are generally issued for large-scale testing of pesticides on more than 10 cumulative acres of land or 1 surface acre of water. Contained within the scope of the regulation, however, is the presumption that small-scale testing, i.e., on not more than 10 cumulative acres of land or 1 surface acre of water, does not require an EUP provided that the crops are destroyed or an appropriate tolerance is in place (40 CFR 172.3(a)). This presumption, however, is caveated not to preclude experimental testing on larger areas in certain circumstances where the purpose of the large acreage test is only to determine the substance's value for pesticidal purposes or to determine its toxicity or other properties, and no benefit from pest control is expected (40 CFR 172.3(b)). In the **Federal Register** of January 22, 1993

(58 FR 5878), EPA issued a proposed amendment to 40 CFR part 172. The proposed amendment would, among other things, modify section 172.3 to clarify that the determination of whether an EUP is required is based on risk/benefit considerations. The amendment would provide that tests conducted on not more than 10 acres of land and 1 surface acre of water are presumed not to involve unreasonable risks, and therefore, do not require an EUP.

FIFRA also authorizes EPA to require data to be submitted to evaluate whether an EUP or registration will be granted. Moreover, under FIFRA, EPA can impose labeling restrictions and FIFRA requires that the pesticide be used in accordance with such labeling restrictions. Under FIFRA section 25(b), EPA may exempt, by regulation, any pesticide determined to be: (1) Adequately regulated by another Federal agency, or (2) of a character which is unnecessary to be subject to the Act in order to carry out the purposes of the Act.

B. FFDCA

The Reorganization Plan of 1970 that created EPA reallocated the authority under FFDCA to regulate pesticide residues in foods and animal feeds to EPA. Pursuant to section 402 of FFDCA, foods that are raw agricultural commodities are deemed to be adulterated if they contain a pesticide chemical which is unsafe within the meaning of section 408(c) of FFDCA. Under FFDCA section 408, any poisonous or deleterious pesticide chemical added to a raw agricultural commodity, that is not "generally recognized as safe" (GRAS), is deemed to be unsafe unless a tolerance, or an exemption from the requirement of a tolerance, for such pesticide chemical is established and the pesticide chemical residue is within the tolerance limits. Section 408 of FFDCA applies to all "pesticide chemicals" which are defined in section 201(q) of FFDCA as:

> any substance which, alone, in chemical combination or in formulation with one or more other substance, is "a pesticide" within the meaning of [FIFRA] . . .and which is used in the production, storage, or transportation of raw agricultural commodities.

Thus, pesticide chemicals subject to regulation under FFDCA are defined by reference to the definition of pesticide under FIFRA.

Section 408 of FFDCA authorizes EPA to set tolerances for pesticide chemical residues on raw agricultural commodities to the extent necessary to protect the public health. In establishing a tolerance, EPA must give appropriate consideration to the following factors: (1) The necessity for the production of an adequate, wholesome, and economical food supply; (2) the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) the opinion submitted with a certification of usefulness under the Act (FFDCA section 408(b)). Thus, as with FIFRA, the regulatory decisions EPA makes under FFDCA section 408 involve a risk/benefit balance. Unlike FIFRA, however, FFDCA only addresses dietary risks to humans and other animals.

Under FFDCA section 408(c), EPA can exempt, by regulation, any pesticide chemical from the necessity of a tolerance when such tolerance is not necessary to protect the public health. In the absence of such an exemption, any pesticide chemical used on raw agricultural commodities is deemed unsafe unless EPA establishes a tolerance for the pesticide chemical residue, and the pesticide chemical residue is within the tolerance limits, or the pesticide chemical is GRAS.

Under FFDCA section 402, food is deemed to be adulterated if it contains any food additive not authorized by a food additive regulation under section 409. Because of the "flowthrough" provision in section 402(a)(2), EPA has interpreted section 409 as applying to pesticide residues in processed food which result from use of the pesticide in or on raw food if the concentration of the pesticide in the processed food is greater than the level set under section 408 for the raw food tolerance. If EPA grants an exemption from the requirement of a tolerance under section 408 for the raw food, residues in the resulting processed food are also exempt even if they are higher than in the raw food. Section 409 also applies to pesticide residues in processed food resulting from direct application of the pesticide to processed food. However, since the plant-pesticides that EPA is addressing would all be present in the plant which would be a raw agricultural commodity, this aspect of section 409 would not come into play. In issuing a food additive regulation under section 409, EPA must determine that the proposed use of the food additive, under the conditions of use specified in the regulation, will be safe. In EPA's view, the determination of whether use of a pesticidal food additive is safe should take into account the net effects of use of the additive on the food supply. These net effects include the benefit of an adequate, wholesome, and economical food supply that may result from a pesticide's use as well as any harm to the food supply that may result from the pesticide's use.

A section 409 food additive regulation is not required for any substance that is GRAS. A GRAS finding must be based either on a record of safe use in food prior to 1958 (when Congress modified FFDCA) or evidence of safety and widespread agreement in the appropriate scientific community (FFDCA section 201(s)).

IV. Rationale and Regulatory Status of Plant-pesticides

A. Introduction

As are all pesticides, all plant-pesticides are potentially subject to EPA's regulatory authority under FIFRA. Since FFDCA defines pesticides in terms of the definition in FIFRA section 2, EPA also has the authority to regulate residues of plant-pesticides under FFDCA sections 408 and 409 (Unit III.). Both FIFRA and FFDCA give EPA the authority to exempt pesticides from regulation through notice and comment rulemaking.

EPA has attempted to identify, for regulatory oversight, those types of plant-pesticides that appear to have greater potential for environmental and/or human health risks. Through FIFRA section 25(b), EPA proposes to exempt certain categories of plant-pesticides that do not warrant oversight. Those plant-pesticides, or categories of plant-pesticides, not exempted would form the scope of EPA's regulatory scrutiny under FIFRA.

FIFRA section 25(b) allows the Agency to exempt a pesticide if it is of a character unnecessary to be subject to the Act in order to carry out the purposes of the Act. For plant-pesticides, the Agency proposes to amend 40 CFR part 152 and to create a new part 174 that would exempt, from regulation under FIFRA, certain categories of plant-pesticides that pose low probability of risk and will not cause unreasonable adverse effects on the environment (See the proposal published elsewhere in todays issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule").

Under FFDCA section 408(c), EPA can establish an exemption from the requirement of a tolerance for a pesticide chemical if the Agency determines that a tolerance is not necessary to protect the public health. The Agency is proposing to exempt, on that basis, certain categories of plant-pesticides from the requirement from a tolerance (described in documents published elsewhere in todays issue of

the **Federal Register** entitled, "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act"; "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants"; "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants"). Those plant-pesticides not exempt would be subject to EPA review under the FFDCA authorities.

The following unit of this statement describes the environmental and human health considerations that the Agency weighed in determining which plant-pesticides to propose for exemption from regulation under FIFRA and FFDCA. Those plant-pesticides that would not be exempt would be subject to regulation.

B. FIFRA

1. *Summary of proposed regulatory status for plant-pesticides.* The following unit summarizes the proposed regulatory status of plant-pesticides under FIFRA. Because of the unique nature of plant-pesticides, the Agency is proposing regulatory definitions that would apply to plant-pesticides only. In addition, the Agency is proposing to exempt certain classes of plant-pesticides from regulation under FIFRA because the Agency believes that they pose low probability of risk and will not cause unreasonable adverse affects (see the proposal published elsewhere in todays issue of the **Federal Register** entitled, "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule").

a. *Definition of plant-pesticide.* EPA is proposing to define "plant-pesticide" under FIFRA as:

> A pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

EPA is including the genetic material necessary to produce the substance in the proposed definition of plant-pesticide for a number of reasons. First, it is the genetic material that is introduced into the plant with the intent that it will ultimately result in a pesticidal effect. Additionally, EPA's regulation of pesticides is based on an evaluation of the potential for unreasonable adverse effects to humans and the environment associated with the use of the pesticidal substance, in this case, the pesticidal substance produced in the plant. Regulation also includes risk management considerations. A focus on the genetic material would permit the Agency to address the potential for the spread of the pesticidal substance in the environment through the spread of the genetic material necessary for the production of the substance. Moreover, the amount of pesticidal substance likely to be produced by the plant is also an important consideration that the Agency may, in some circumstances, be able to address through the inclusion of genetic material in the definition of plant-pesticide. In addition, including the genetic material in the definition of plant-pesticide would permit the Agency to address plant-pesticides during stages of the plant's life cycle or in plant parts where the pesticidal substance itself is not produced or is produced in very small amounts (e.g., in pollen or seed). In these cases, it is technically easier to verify the presence of the genetic material than the pesticidal substance.

b. *Active and inert ingredients.* The regulation of pesticides under FIFRA entails the identification of "active ingredients" and "inert ingredients." Under FIFRA section 2, the term active ingredient means ". . .an ingredient which will prevent, destroy, repel, or mitigate any pest. . . [or acts as a plant regulator, defoliant or desiccant]." The term inert ingredient means ". . .an ingredient which is not active." EPA recognizes that plant-pesticides have certain characteristics that are different from those of more traditional chemical pesticides. EPA believes that the overall characteristics of plant-pesticides require specifically tailored active and inert ingredient definitions.

In light of this consideration, EPA proposes to use the following definitions for active and inert ingredients for plant-pesticides.

"Active ingredient," when referring to plant-pesticides only, means a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

"Inert ingredient," when referring to plant-pesticides only, means any substance, such as a selectable marker, other than the active ingredient, and the genetic material necessary for the production of the substance, that is intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient.

Note that the plant-pesticide active ingredient is the plant-pesticide and therefore the proposed definition of active ingredient for plant-pesticides is the same as the definition of plant-pesticide. The plant-pesticide product includes both the active and inert ingredients.

The definition of plant-pesticide and the active and inert ingredient definitions would include all of the genetic material "necessary for the production" of the pesticidal and inert substance. The following genetic regions are considered "necessary for the production" of the plant-pesticide, active and inert substances: (1) The genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance and (2) regulatory regions such as promoters, enhancers, and terminators.

The genetic material can either directly encode for the pesticidal substance or may encode for enzymes that lead to the production of a pesticidal substance (e.g., phenylalanine ammonia-lyase (PAL) catalyzes the first reaction in the synthesis of such phytoalexins as pterocarpans in *Leguminosae* and furanocoumarins in *Solanaceae* and *Umbelliferae*; Ref. 6). It might also include genetic regions encoding for RNA that acts as the pesticidal substance or leads to the production of the pesticidal substance (e.g., antisense mRNA). The active and inert ingredients would also include any regulatory regions, such as promoters, that control the expression of the genetic material encoding for the pesticidal or inert substance or leading to the production of the pesticidal or inert substance and are introduced into the plant along with that gene.

The genetic material "necessary for the production" of the plant-pesticide, active and inert substances does not include genetic regions that are not involved in DNA expression (i.e., noncoding, nonexpressed sequences such as linkers, adapters, homopolymers and sequences of restriction enzyme recognition sites). However, the Agency would require information concerning these sequences if it determines that such information is necessary for the evaluation of the active or inert ingredient.

There may be genetic material encoding other functions (e.g., genetic material intended to alter the amount of carbohydrate in the plant) that are introduced into the plant along with the active and inert ingredients. These functions would be subject to Food and Drug Administration (FDA) authorities.

c. *Exemptions under FIFRA.* EPA has attempted to identify those types of plant-pesticides that have greater potential for environmental and/or

human health risks and to focus its regulatory scrutiny on these plant-pesticides. To exempt from regulation those plant-pesticides having less potential for risk, EPA is proposing to employ its exemption authority under FIFRA section 25(b). FIFRA section 25(b)(2) allows the Agency to exempt a pesticide from FIFRA regulation if it is of a character unnecessary to be subject to the Act in order to carry out the purposes of the Act. Through FIFRA section 25(b)(2), EPA proposes to exempt, from FIFRA regulation, certain categories of plant-pesticides that EPA believes pose low probability of risk and are not likely to cause unreasonable adverse effects even in the absence of any regulatory oversight under FIFRA and, thus, are of a character unnecessary to be subject to the Act. Those plant-pesticides not exempted would form the scope of EPA's regulatory scrutiny under FIFRA.

EPA finds that the plant-pesticides it is proposing to exempt have a low probability of risk and have potential benefits associated with them (e.g., economic benefit to farmers and reducing the need for chemical pesticides) that outweigh any potential risks associated with them, and that the low probability of risk does not justify the cost of regulation. For a detailed description and analysis of the proposed exemptions under FIFRA, see the proposal published elsewhere in todays issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide Fungicide and Rodenticide Act; Proposed Rule."

(i) *Exemption of plant-pesticides derived from closely related plants.* The Agency is proposing to concentrate its regulatory efforts under FIFRA on those plant-pesticides that are new to the plant and, thus, have the greatest potential for exposing nontarget organisms to a new pesticidal substance. The Agency is proposing to exempt from FIFRA regulation those plant-pesticides that are normally a component of (not new to) the plant. The approach EPA is proposing to use to capture the concept of "normally a component" is based on the concept of sexual compatibility. The standard of sexual compatibility is embodied in the following language from the proposed regulatory text:

[Plant-pesticides are exempt from FIFRA requirements if:]

. . .The genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from plants that are sexually compatible with the recipient plant and has never been derived from a source that is not sexually compatible with the recipient plant;. . .

Key definitions associated with this language are:

"Bridging crosses" between plants means the utilization of an intermediate plant in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote.

"Genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance" does not include regulatory regions or noncoding, nonexpressed nucleotide sequences.

"Regulatory region" means genetic material that controls the expression of the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include promoters, enhancers, and terminators.

"Sexually compatible," when referring to plants, means capable of forming a viable zygote through the fusion of two gametes, including the use of bridging crosses or wide crosses between plants.

"Source" means the donor of the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance.

"Wide crosses" between plants means to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre- and post- pollination hormone treatments, manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures or any other technique that the Administrator determines meets this definition.

EPA is also proposing for discussion two alternative options for describing this category of plant-pesticides in plants (see Unit IV.B.2. of this document and the proposal published elsewhere in today's issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule").

(ii) *Exemption of plant-pesticides that act primarily by affecting the plant.* One of EPA's primary goals in regulating pesticides is to control the potential for adverse effects of pesticides on nontarget organisms. An important component in the evaluation of this potential is the way in which the pesticidal substance acts on the target pest since it would also likely affect nontarget organisms through the same mechanism. Based on this rationale, the Agency is proposing to exempt from FIFRA regulation plant-pesticides that are not directly toxic to the target pest. This proposed exemption is embodied in the following language from the proposed regulatory text:

[Plant-pesticides are exempt from FIFRA requirements if:]

. . .The pesticidal substance acts primarily by affecting the plant so that the target pest is inhibited from attaching to the plant, penetrating the plant, or invading the plant's tissue in at least one of the following ways:

(1) The pesticidal substance acts as a structural barrier to attachment of the pest to a host plant, a structural barrier to penetration of the pest into a host plant, or a structural barrier to spread of the pest in a host plant, for example, through the production of wax or lignin, or length of trichomes (plant hairs); or

(2) The pesticidal substance acts in the host plant to inactivate or resist toxins or other disease-causing substances produced by the target pest; or

(3) The pesticidal substance acts by creating a deficiency of a plant nutrient or chemical component essential for pest growth on/in the host plant.

(iii) *Exemption of coat proteins from plant viruses.* Coat proteins are those substances that viruses produce to encapsulate and protect their genetic material. When the genetic material encoding the coat protein from a plant virus is introduced into a plant's genome, the plant is able to resist infections by the virus (termed viral coat protein mediated resistance or vcp-mediated resistance). The Agency proposes to exempt the genetic material encoding the coat protein and the coat protein itself when these are introduced into a plant to effectuate vcp-mediated resistance. This proposed exemption is embodied in the following regulatory text:

[Plant-pesticides are exempt from FIFRA requirements if:] . . .The pesticidal substance is a coat protein from a plant virus. . .

EPA is also proposing for discussion an alternative, more restrictive exemption for coat proteins from plant viruses used in viral coat protein mediated resistance (see Unit IV.B.2. of this document and the proposal published elsewhere in todays issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule").

2. *Rationale for Proposed Exemptions under FIFRA.* As with traditional pesticides, the underlying considerations in analyzing risks posed by plant-pesticides are the potential for

exposure to the pesticidal substance and hazards of the pesticidal substance to humans and other nontarget organisms. For plant pesticides, exposure and hazard will be determined by the chemical and toxicological properties of the pesticidal substance and the biological characteristics of the plant that is producing the substance.

The properties of the plant-pesticide, including the mechanism by which it affects the target pest, will determine the potential for hazards to nontarget organisms. The type of organism exposed to the plant-pesticide will be determined by the characteristic of the plants that produce the substance and the environment where the plants are grown; e.g., whether the production of the substance is limited to particular plant parts, the organisms that normally associate with the plant, and the acreage and location planted. An important consideration not seen with traditional pesticides is the potential for spread of the plant's genetic material. Because plants can reproduce sexually and/or asexually, unintentional exposure to the plant-pesticide could occur in both the agro- or natural ecosystems, particularly if wild relatives acquire the ability to produce the plant-pesticide through successful hybridization.

Such hazard and exposure considerations form the bases of the three exemptions that the Agency is proposing for plant-pesticides under FIFRA (see the proposal published elsewhere in todays issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule" for more detailed analyses of these exemptions).

The benefits associated with use of some categories of plant-pesticides include the economic benefit to farmers for use of plant-pesticides in circumstances where traditional pesticides may not be as effective (e.g., for some systemic plant pests) or may be more expensive, thus increasing crop yield and/or reducing farmers' costs. An additional benefit is the environmental benefit associated with potential reduced use of pesticides that may be less environmentally benign than these plant-pesticides.

a. *Exemption of plant-pesticides derived from closely related plants.* A primary consideration in evaluating plant-pesticides is the potential for new exposures of nontarget organisms to the pesticide. If a plant normally produces a pesticidal substance, organisms that normally come in contact with the plant have likely been exposed to that substance in the past, perhaps over long periods of time. No new exposures would be expected to occur.

In contrast, if a plant-pesticide is new to a plant, the organisms that come in contact with the plant may never have been exposed to the substance. For instance, certain spiders produce a toxin that is targeted for their insect prey. Plants are not known to produce this toxin in nature nor in cultivation. If this toxin were to enter the gene pool of specific plants, organisms that had never previously been exposed to the toxin could now be exposed. Prior to the introduction of the toxin into these plants, only the insect prey of the spider would potentially be exposed to the toxin. If plants could now express the toxin, a different or larger group of organisms could be exposed to it, possibly resulting in adverse effects to these organisms. For instance, insects or animals that feed on the plant could be exposed to the toxin. If the toxin is found in pollen, pollinators could also be exposed.

EPA proposes to concentrate its regulatory efforts under FIFRA on those plant-pesticides that are new to the plant and thus have the greatest potential for exposing nontarget organisms to a new pesticidal substance. The Agency would consider plant-pesticides produced in sexually compatible plants to be least likely to result in these new exposures (see the proposal published elsewhere in todays issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule"). Sexually compatible plants are more apt to share common traits than are unrelated plants. It is a common expectation that similarity is associated with the degree of relatedness. Natural hybridization and selection have produced groups of plants which have a common gene pool. Generations of artificial hybridization practiced to produce improved crops for cultivation have tended to increase the extent of relatedness among elements of a broader segment of agricultural plants. Since traits can be passed through a plant population by sexual recombination, it is reasonable to predict that, in a sexually compatible population, new exposures of organisms that associate with plants in the population to the pesticidal substance is unlikely.

The practice of saving seed from desirable plants has been going on for thousands of years and controlled crosses to produce plant hybrids have been documented since the eighteenth century. Since the rediscovery of Mendel's work on the inheritance of traits, there is a base of experience of 50 to 100 years of breeding for most major crops. During that time, it has been common agricultural practice to cross sexually compatible wild relatives with crop plants to develop crop varieties with better pest resistance. Techniques such as genetic mapping reveal the presence of genetic *loci* in cultivated plants that previously were considered to be present only in the wild species. Sexually compatible crop varieties are also crossed with each other to achieve better pest resistance in their progeny. Because of these common practices, the potential for significantly different environmental exposures is likely to be low.

EPA proposes to extend the concept of sexual compatibility to include wide crosses because wide crosses are commonly used to expand the gene pool for varietal improvement. EPA believes that the fact that a wide cross produces a viable zygote indicates a fairly high degree of relatedness between the parental plants. However, for regulatory purposes it is somewhat difficult to define what constitutes a wide cross in a definitive way since techniques may change over time. EPA is thus proposing to define, for the purposes of this rulemaking, wide crosses based on existing techniques with the provision that new techniques can be added if they meet the definition.

A second approach that EPA is considering for defining when a plant-pesticide is new to the plant is a standard based on taxonomy. Under this approach, the standard would rely on the taxonomic grouping of genus; plant-pesticides moved between plants in the same genus would be exempt. The assumption under this approach is that the genus grouping correlates with a relatively high degree of relatedness among plants even though not all plants in a genus are sexually compatible.

A third approach EPA is considering combines the above two standards of taxonomy and sexual compatibility. The standard under this option would rely primarily on the taxonomic grouping of genus as a measure of relatedness. Recognizing that some plants that are sexually compatible are classified in different genera and assuming that sexual compatibility is correlated with a high degree of relatedness, EPA also includes a provision extending the exemption to include plant-pesticides moved between sexually compatible plants even if the plants are classified in different taxonomic genera.

For all of the approaches presented in this unit, the Agency has evaluated whether changes in the levels of plant-pesticides that plants normally produce would warrant regulation under FIFRA.

(Ref. 1 and **Federal Register** document entitled "Plant-pesticides Subject to the Federal Insecticide Fungicide and Rodenticide Act; Proposed Rule" for a more thorough analysis of this issue.) The Agency's analysis indicates that changes in the levels of such plant-pesticides expressed by a plant could result in increased or decreased exposures of nontarget organisms to a plant-pesticide. However, EPA believes, for the reasons outlined below, that the potential for unreasonable adverse effects from these exposures is low and these types of plant-pesticides do not warrant regulation under FIFRA.

In deciding whether and how to regulate such plant-pesticides, EPA first considered whether an increase in the levels of such plant-pesticides is likely to exceed the ranges normally found within and between plant varieties (both cultivated and uncultivated). EPA believes that increases in the levels of such plant-pesticides are not likely to result in overall significantly different exposures of nontarget organisms to the pesticide. The level of production of pesticidal substances normally produced by plants varies among related plants because of differences in genetic makeup and environmental conditions. EPA also considered the extent to which any substance can be increased in cultivated plants without unwanted effects on other, desirable characteristics of the plant (e.g., yield or palatability of fruit). In general, breeders balance all of these characteristics in developing marketable plant varieties. Considerations of characteristics such as yield could serve to mitigate against exceeding certain ranges of pesticide levels. EPA anticipates that the majority of plants with modified levels of plant-pesticides will fall within existing ranges of pesticide levels and does not anticipate that increasing the level of a plant-pesticide that is normally a component of a plant would lead to significantly different spectrum of exposure to the plant-pesticide.

b. *Exemption of plant-pesticides that act primarily by affecting the plant.* As discussed previously, an important component in evaluating the potential for adverse affects on nontarget organisms is the way in which the pesticidal substance acts on the target pest. A pesticidal substance that acts directly on the target pest through a toxic mechanism of action might also exert a similar effect on other organisms. For example, a substance that acts by inhibiting DNA synthesis of the pest could inhibit DNA synthesis in other nontarget organisms.Toxic mechanisms of action include, but are not limited to, those that affect: (i) membrane permeability, (ii) cell division, (iii) gene expression, (iv) DNA replication, or (v) other metabolic functions (Ref. 4).

Pesticidal substances can also act through mechanisms that are less likely to be directly toxic. Although it is possible for these substances to adversely affect nontarget organisms, the Agency believes that, in most cases, they pose significantly lower levels of environmental risk than plant-pesticides with a generalized toxic mechanism of action. For example, if a plant is modified so that it can counter specific disease-producing compounds by inactivating them, it is less likely that organisms that interact with the plant in other, more beneficial ways will be affected. Similarly, a plant may produce defense structures such as layers of cork cells in response to microbial infections. These structures form a barrier to further penetration by the pests and may block the spread of any toxins. Those organisms that do not stimulate this response are not likely to be adversely affected.

Plant-pesticides that are less directly toxic generally act primarily by affecting the plant so that the pest is inhibited from attaching to the plant, penetrating the plant's surface, or invading the plant's tissue. The Agency believes that it would be appropriate to exempt from regulation, under FIFRA, plant-pesticides that act through mechanisms such as these. (See the proposal published elsewhere in todays issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule" for a more detailed discussion of this exemption.) EPA believes that by focusing its regulatory attention on plant-pesticides that act through toxic mechanisms, it will be able to focus on those plant-pesticides presenting higher levels of risk potential.

c. *Exemption of coat proteins from plant viruses.* The Agency is proposing to exempt the genetic material encoding the viral coat protein and the coat protein itself when these are introduced into a plant to effectuate viral coat protein mediated resistance. A more detailed discussion of the Agency's assessment of the risks and benefits of viral coat proteins can be found in the **Federal Register** document entitled, "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule." Major points of the analysis are summarized here.

The Agency's proposal is made in light of a number of considerations which, when taken together, bring EPA to the conclusion that coat proteins from plant viruses generally pose a low probability of risk and would not pose unreasonable adverse effects even in the absence of any regulation under FIFRA. These considerations include the low potential for adverse affects to nontarget organisms and the potential benefits of utilizing vcp-mediated resistance.

Environmental benefits associated with the use of viral coat proteins include the reduction of the use of chemical pesticides for viruses that are spread by vectors (usually insects). Chemical pesticides are used for those crop plants where the most effective method of protection against viral attack is by controlling the vector. These pesticides may not be environmentally benign. The expression of viral coat proteins by plants for protection from viral infection would likely reduce the amount of chemical pesticide used to control the vectors.

In addition to environmental benefits associated with the use of viral coat proteins, an effective method for controlling virus infection will have economic benefits. Plant viruses create economic losses for a vast variety of crops by reducing yields and negatively affecting the quality of the crop. Yield losses and quality effects for a specific crop may vary depending on the host plant and strains of the virus present, the incidence and activity of vectors, timing of the infection, health and nutritional state of the plant, and weather (Ref. 8).

Presently, growers may need to use several control methods during a crop season in an attempt to prevent viral infection and dissemination, primarily by planting virus free material (for mechanically transmitted viruses) and by controlling plant virus vectors, such as insect populations (for vector transmitted viruses). Insecticides, nematicides, and fungicides are all used for vector control with varying success, depending upon the virus/vector relationship and vector efficiency. Plants developed through conventional breeding techniques offer some degree of virus resistance. Such resistance may not be uniform or the virus may develop new strains. However, breeding for resistance has not been successful for the majority of field crops and, in particular, vegetable crops that are severely affected by viruses (Ref. 8).

In enabling plants to resist viral attack, viral coat proteins act in a very specific fashion, apparently adversely affecting only viruses by blocking or limiting their ability to infect, replicate, and/or translocate within the plant. This specificity minimizes the potential for viral coat proteins produced in plants to adversely affect nonviral organisms. In addition, plants in nature and in the

agro-ecosystem frequently exhibit viral infections; nontarget organisms, including humans, have been and continue to be exposed to the viral coat proteins with no observed adverse effects.

The possibility that environmental risk might be associated with the use of vcp-mediated resistance was discussed at the December 18, 1992, FIFRA SAP Subpanel meeting. EPA agrees with the conclusions of the SAP Subpanel and in developing its proposal has utilized the advice of the Subpanel to supplement EPA's own evaluation of the scientific literature (Ref. 2). The considerations discussed at this meeting included: (1) The potential for new viruses to be formed through transcapsidation (also called heterologous encapsidation) and recombination; (2) the potential for synergistic infections; (3) the potential for seed transmission; and (4) the potential for the development of selective advantage in wild relatives through successful hybridization with the plant producing the viral coat protein. (See Unit VIII. of this document for a more detailed discussion of the SAP report and the proposal published elsewhere in todays issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule" for discussion of the Agency's preferred proposed exemption and the alternative approach to viral coat proteins).

With regard to selective advantage, the Subpanel report noted that while the series of events that must occur for the wild plant to acquire a selective advantage from vcp-mediated resistance coat proteins is rather improbable, such a series of events is not impossible. An alternative option presented by the Agency offers a more limited exemption of vcp-mediated resistance coat proteins to address the possibility that plants acquiring the vcp-mediated resistance genes might also acquire a selective advantage. With regard to the alternative option, the Agency has defined a set of criteria that would be used to identify those viral coat protein/plant combinations that have the greatest potential for outcrossing to wild, free living relatives and thus have the possibility endowing these wild relatives with a competitive advantage. Viral coat proteins that potentially could be outcrossed to wild relatives would be subject to regulation while those viral coat protein/plant combinations with a lesser or no probability of outcrossing would be exempt from regulation. The language covering this alternative is as follows.

Coat proteins from plant viruses [would be exempt] if the genetic material necessary to produce a coat protein is introduced into a plant's genome and the plant has at least one of the following characteristics:

(1) The plant has no wild relatives in the United States with which it can successfully exchange genetic material, i.e., corn, tomato, potato, soybean, or any other plant species that EPA has determined has no sexually compatible wild relatives in the United States.

(2) It has been demonstrated to EPA that the plant is incapable of successful genetic exchange with any existing wild relatives (e.g., through male sterility, self-pollination).

(3) If the plant can successfully exchange genetic material with wild relatives, it has been empirically demonstrated to EPA that existing wild relatives are resistant or tolerant to the virus from which the coat protein is derived or that no selective pressure is exerted by the virus in natural populations.

For the purposes of this option, "introduced into the plant's genome" would mean movement of nucleotide sequences into the genetic material in a plant cell's nucleus, mitochondria, chloroplasts and any other plastids. "Successful genetic exchange" would mean capable of forming zygotes viable in the laboratory and/or field through the fusion of two gametes.

C. FFDCA

1. *Summary of regulatory status.* As indicated previously, the Agency has available, under FFDCA section 408(c), the authority to exempt plant-pesticides from the requirement of a tolerance if such tolerance is not necessary to protect the public health (Unit III). The Agency is proposing that such a finding is appropriate for three classes of plant-pesticides: (1) Categories of pesticidal substances produced in plants that do not result in new dietary exposures based upon the source from which the pesticidal substance is derived; (2) nucleic acids produced in plants as part of a plant-pesticide; and (3) coat proteins from plant viruses when they are produced in plants. (For more detail on these proposed exemptions refer to the following **Federal Register** documents: "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act"; "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants"; "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants").

a. *Exemption from the requirement of a tolerance for categories of plant-pesticides that would not result in new dietary exposures.* Under this exemption, the Agency is proposing to exempt from the requirement of a tolerance two categories of plant-pesticides: (1) Plant-pesticides produced in food plants and derived from closely related food or non-food plants and (2) plant-pesticides produced in food plants and derived from food plants that are not closely related to the recipient food plant and would not result in significantly different dietary exposures when produced in the recipient food plant. The proposed exemption is as follows:

(a) Residues of pesticidal substances produced in living plants as plant-pesticides are exempt from the requirement of a tolerance if the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from plants that are sexually compatible with the recipient plant and has never been derived from a source that is not sexually compatible with the recipient plant;

(b) Residues of pesticidal substances produced in living plants as plant-pesticides are exempt from the requirement of a tolerance when the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from plants that are not sexually compatible with the recipient plants if:

(1) The genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from food plants; and

(2) The pesticidal substances would not result in significantly different dietary exposures.

For the purposes of this exemption, the following definitions apply:

"Bridging crosses" between plants means the utilization of an intermediate plant in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote.

"Food plant" means a plant which, either in part or *in toto* is used as food by humans.

"Genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance" does not include regulatory regions or noncoding, nonexpressed nucleotide sequences.

"Living plant" means a plant that is alive, including periods of dormancy, and all viable plant parts/organs involved in the plant's life cycle.

"Major crops for human dietary consumption" means wheat, corn,

soybeans, potatoes, oranges, tomatoes, grapes, apples, peanuts, rice, beans, and any other crops that the Agency has determined is a major crop for human dietary consumption.

"Noncoding, nonexpressed nucleotide sequences" means the nucleotide sequences are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

"Recipient plant" means the plant into which the plant-pesticide is introduced and in which the plant-pesticide is produced.

"Regulatory region" means genetic material that controls the expression of the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include promoters, enhancers, and terminators.

"Result in significantly different dietary exposure" means:

(1) The pesticidal substance is produced in inedible portions of the source food plant, but, in the recipient plant, the pesticidal substance is present in the plant's edible portions.

(2) The pesticidal substance is produced in the immature, but not in the mature, edible portions of the source food plant, but, in the recipient plant, the pesticidal substance is present in the mature, edible portions.

(3) The pesticidal substance is from a source food plant normally cooked or processed prior to consumption and is produced in a recipient plant that is not normally cooked or processed prior to consumption.

(4) The pesticidal substance is derived from a source food plant that is not a major crop for human dietary consumption and is introduced into a recipient plant that is a major crop for human dietary consumption.

"Sexually compatible," when referring to plants, means capable of forming a viable zygote through the fusion of two gametes, including the use of bridging crosses or wide crosses between plants.

"Source food plant" means the donor of the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance.

"Wide crosses," between plants, means to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre- and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures, or any other technique that the Administrator determines meets this definition.

The Agency is also proposing an alternative approach that uses a standard that relies primarily on the taxonomic grouping of genus as a measure of relatedness between plants (for more discussion of this alternative approach, see Unit IV.C.2. of this document and the proposal published elsewhere in todays issue of the **Federal Register** entitled "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act."

b. *Exemption from the requirement of a tolerance for nucleic acids produced in plants as part of a plant-pesticide.* This proposed exemption would exempt nucleic acids (i.e., deoxyribonucleic acid (DNA) and ribonucleic acid (RNA)) from the requirement for a food tolerance when produced in plants as part of a plant-pesticide active or inert ingredient (refer to Unit IV.B.1. of this document for a discussion of the definition of plant-pesticide active and inert ingredients). The proposed exemption is as follows:

> Residues of nucleic acids produced in living plants as part of a plant-pesticide active or inert ingredient, including both deoxyribonucleic and ribonucleic acids, are exempt from the requirement of a tolerance.

For the purposes of this exemption, "nucleic acids" means ribosides or deoxyribosides of adenine, thymine, guanine, cytosine, and uracil and the polymers of these ribosides and deoxyribosides and does not apply to nucleic acid analogues.

c. *Exemption from the requirement of a tolerance for viral coat proteins produced in plants.* EPA proposes to exempt from the requirement of a tolerance coat proteins from plant viruses when they are produced by plants to enable the plants to resist viral infection. The proposed exemption is as follows:

> Residues of coat proteins from plant viruses, or segments of the coat proteins, produced in living plants as plant-pesticides are exempt from the requirement of a tolerance.

2. *Rationale for exemptions under FFDCA.* There are circumstances where EPA believes that plant-pesticides should be reviewed by EPA either to set a tolerance or issue an exemption from the requirement of a tolerance. In general, EPA believes that plant-pesticides resulting in significantly different dietary exposures than those that already occur should be subject to EPA review under FFDCA tolerance procedures.

a. *Exemption from the requirement of a tolerance for categories of plant-pesticides that would not result in new dietary exposures.* Many substances having pesticidal activity occur naturally in the edible parts of plants (i.e., they are inherent to the plant) and have long been accepted as part of the human diet. The safety of foods containing these substances is demonstrated by extensive consumption and experience. For many foods, the inherent toxicants they may contain, including pesticidal substances, are known (Ref. 5). Also, the established practices that plant breeders employ in selecting and developing new plant varieties, such as chemical analyses, taste-testing and visual analyses, have historically proven to be reliable for ensuring food safety. That there are few examples of new plant varieties causing food safety concerns, despite the large numbers of new varieties introduced into commerce each year, is a reflection of the effectiveness of this process. Moreover, consumer experience with the handling and preparation of food from these plants contributes to the safety of food from these plants.

(i) *Plant-pesticides from closely related plants.* This proposed exemption is based upon the premise that new dietary exposures would not likely arise for plant-pesticides produced in food plants if the genetic material leading to the production of the plant-pesticide is derived from closely related plants. In establishing this exemption, EPA is proposing to use a standard that is similar to the standard proposed for an exemption for plant-pesticides under FIFRA (see Unit IV.B. of this document). That standard would be sexual compatibility. Under both statutes, this standard would be used as a measure of relatedness between plants. However, under FFDCA, the standard of sexual compatibility must be examined specifically within the context of the food supply and dietary consumption. The Agency believes, based on the experience with sexually compatible plants (see Unit IV.B. of this document), that most plant varieties developed by plant breeders using genetic material from plants that meet the sexually compatible standard produce food that is safe for human consumption and/or that appropriate processing procedures are widely known and routinely used by consumers in preparation of food from such sources.

As under FIFRA, EPA proposes to extend the concept of sexual compatibility to include wide crosses because wide crosses are commonly used to expand the gene pool for varietal improvement and, as discussed

earlier, EPA believes that the fact that wide crosses can produce a viable zygote indicates a fairly high degree of relatedness between parental plants.

The Agency is considering, for this exemption, a second option based primarily on the taxonomic standard of genus rather than on sexual compatibility. Under this approach, a plant-pesticide would be exempt if it were derived from a plant within the same genus as the recipient plant. The Agency recognizes that some plants that are closely related (as evidenced by sexual compatibility) are not classified in the same genus. Under this alternative option, the Agency would extend the exemption to plant-pesticides derived from plants in these populations, as well as to intrageneric plant-pesticides. Therefore, if a plant-pesticide is derived from a plant outside of the same genus, sexual compatibility between the two plants would need to be demonstrated. The language defining this option would be as follows.

[Residues of pesticidal substances produced in living plants as plant-pesticides are exempt from the requirement of a tolerance if:]

The genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance:

(1) Is derived from plants that are within the same genus as the recipient plant [regardless of sexual compatibility] or, is derived from plants that are sexually compatible with the recipient plant; and

(2) Has never been derived from a source outside the same genus that is not sexually compatible with the recipient plant.

For a more detailed analysis of EPA's preferred approach and Option 2, refer to the **Federal Register** document published elsewhere in today's issue of the **Federal Register** entitled, "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance under the Federal Food, Drug, and Cosmetic Act."

(ii) *Plant-pesticides derived from food plants that are not closely related with the recipient plant.* There are circumstances where experience with exposure can be inferred for plant-pesticides introduced into food plants from other food plants that are not closely related to the recipient plant. For plant-pesticides derived from a *food plant* that is not sexually compatible with the recipient food plant, there is experience with exposure because both plants have contributed to the food supply. Thus, the Agency is proposing to exempt from the requirement of a tolerance plant-pesticides derived from food plants that are not closely related to the recipient plant, if there would not be significantly different dietary exposures when the plant-pesticide is produced in the recipient food plant.

The Agency has defined a set of criteria to determine whether significantly different dietary exposures from the these plant-pesticides will occur. For example, if a pesticidal substance is normally only produced in inedible portions or immature fruit of the food plant, the Agency would require a tolerance review if the modified food plant were to produce that substance in its mature fruit or edible portions. For example, tomatine is a toxicant produced in much higher amounts in immature tomato fruit (that is normally eaten) than it is in the fruit. If the genetic material leading to the production of tomatine were introduced into a plant for pesticidal purposes such that the tomatine were produced in the mature fruit as it is in the immature fruit, the Agency would need to conduct a tolerance review to determine whether a tolerance is necessary to protect the public health. Similarly, if a pesticidal substance is produced in a food that is almost always cooked or processed prior to consumption, the Agency would want to conduct a tolerance review if another food plant that is not cooked or processed prior to consumption is modified to produce the substance. For example, some beans are rich in lectins, glycoproteins that are natural toxicants. Soaking and cooking the beans destroys the lectins. If the genetic material encoding lectins were transferred, for pesticidal purposes, from beans to a plant which is not normally cooked (e.g., lettuce), the Agency would need to conduct a tolerance review. A significantly different dietary exposure could also result if a widely consumed food staple such as corn is modified to produce a pesticidal substance from a food crop with minor consumption such as eggplant.

EPA is also considering adding another criterion to the exemption from the requirement of a tolerance for categories of plant-pesticides that would not result in new dietary exposures (Unit IV.C.1.a. of this document). This criterion would address the potential for allergenicity of plant-pesticides in food. Under this criterion, if a plant-pesticide is derived from a commonly allergenic food, the plant-pesticide would not be exempt from tolerance requirements and the Agency would conduct a tolerance review on a case-by-case basis to determine whether to establish an exemption from the requirement of a tolerance, establish a tolerance, or deny a tolerance. Some examples of foods that commonly cause an allergenic response are milk, eggs, fish, crustacea, molluscs, tree nuts, wheat, and legumes (particularly peanuts and soybeans).

b. *Nucleic acids in plants.* The Agency is also proposing to exempt from the requirement of a tolerance nucleic acids produced in plants as part of plant-pesticide active or inert ingredients. Nucleic acids (deoxyribonucleic and ribonucleic acid) are present in the cells of every living organism, including plants, microorganisms, and animals. Because nucleic acids are ubiquitous in the food supply and lack any toxicity when they are consumed in food, EPA believes that a tolerance for nucleic acids is not necessary to protect the public health (see the proposal published elsewhere in todays issue of the **Federal Register** entitled "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants" for a more detailed discussion).

c. *Coat proteins from plant viruses.* The Agency's proposal for exempting coat proteins from plant viruses is based on virus-infected plants having always been a part of the human and domestic animal food supply without detectable adverse human health effects. There is no evidence of any plant virus being able to replicate in mammals or other vertebrates. In addition, the exemption will only apply when the portion of the viral genome coding for the whole coat protein or a sub-component of the coat protein will be expressed in the plant. This portion of the viral genome by itself is incapable of forming infectious particles. Since whole, intact plant viruses are not known to cause untoward human health effects, it is reasonable to assume that a subunit of these viruses will not be harmful (see the proposal published elsewhere in todays issue of the **Federal Register** entitled "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants" for a more detailed discussion).

D. Plant-pesticides and Plant Regulators

As discussed in Unit III. of this document, FIFRA section 2(u) defines "pesticide" as: ". . .(2) any substance or mixture of substances intended for use as a plant regulator, defoliator, or desiccant. . . ." FIFRA section 2 also defines "plant regulator" as ". . .any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of the plants or the produce thereof. . . ." With

regard to substances applied to plants, this definition has been interpreted to include, for example, plant hormones (e.g., auxin, gibberellin, cytokinin and ethylene). In the area of plant-pesticides, the issue arises as to which substances produced by a plant should be considered plant regulators, as a result of a change in the physiology of the plant, and therefore, pesticides, subject to regulation.

At the time that the term "plant regulator" was added to the definition of pesticide, in 1959, Congress addressed substances applied to plants but did not address how the definition applied to substances produced in plants. EPA believes this is because the technology to develop plant varieties expressing substances using genetic information derived from diverse sources (e.g., outside the plant kingdom) was not in existence, and thus, Congress did not provide direct guidance on the implications of the definition of plant regulator for substances produced in plants.

EPA, therefore, believes that it has the discretion to develop a reasonable approach to defining what constitutes a plant regulator for substances produced in plants. In developing this interpretation, EPA looked at previous Congressional action relating to "plant regulators," plant science, the traditional roles of EPA and FDA in this area, and the extent to which risk concerns would go unaddressed if EPA did not include certain plant substances in the definition of "plant regulator."

While Congress has not spoken on the full extent of the definition of "plant regulator," it has given some guidance on what it does not consider to be plant regulators through exclusions to the definition in FIFRA itself. For example, Congress specifically excluded "substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments." Arguably, Congress recognized that no purpose would be served by requiring substances such as plant nutrients to be regulated as "pesticides."

In 1972, Congress added the vitamin-hormone horticultural product exclusion to the definition of plant regulator. This exclusion provides that "the term plant regulator shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, *intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are non-toxic, nonpoisonous in the undiluted packaged concentration*" (FIFRA section 2(v) emphasis added). This exclusion can be used as a reasonable starting point for EPA's identification of the types of substances that fall within its jurisdiction.

Another factor that the Agency considered in developing its approach to "plant regulators" was harmonization with the traditional split between EPA and FDA jurisdiction under FFDCA. The reorganization plan of 1970 generally placed the FFDCA responsibility for setting tolerances for pesticide residues in food under EPA's jurisdiction and the responsibility for regulating all other substances in food under FDA's jurisdiction. FDA traditionally regulates, for example, substances in food that are used for improved food processing or improved nutritional content. The issue here, therefore, is not whether or under what statutory authority a substance will be regulated. Rather, the issue is who will regulate. If a substance is defined by FIFRA as a pesticide, it is subject to EPA's regulatory authority. If the substance is not a pesticide under FIFRA, FDA has regulatory responsibility. EPA believes it is reasonable to develop a plant regulator interpretation for plant-pesticides that provides for FDA to regulate the types of substances that it has experience and expertise in regulating and that avoids regulation by EPA as "pesticides," substances that relate to nutrition and food quality. Accordingly, EPA is proposing the following interpretation of "plant regulator" for the purpose of determining which substances produced by a plant as a result of changes in the plant's physiology should be considered to be "pesticides," subject to EPA's regulatory jurisdiction. EPA believes that this interpretation is consistent with Congress' intent of including a category of substances they termed "plant regulators," or at least certain types of growth regulators, within the definition of pesticide.

A substance that is produced in a plant as a result of a change in the plant's physiology would be considered a plant regulator if:

It is intended to accelerate or retard the rate of growth or rate of maturation, or alter the behavior of the plants and meets one of the following criteria:

(1) Is a plant hormone.

(2) Acts to prevent, destroy, repel, or mitigate a pest.

(3) Is toxic in concentrations found in the plant (undiluted package).

Plant hormones that are produced in plants as the result of an intentional change in the plants' physiology would be considered plant regulators. As plant regulators, they would also be considered a plant-pesticide and under EPA's authority. However, EPA believes that some of these substances would be candidates for exemption from regulation under FIFRA under the exemption of plant-pesticides derived from closely related plants (see Unit IV.B.1.c.i. of this document and the proposal published elsewhere in today's issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule"). EPA is also considering extending the exemption of plant-pesticides that act primarily by affecting the plant to include substances such as plant hormones (see Unit IV.B.1.c.i. of this preamble and the proposal published elsewhere in today's issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule").

A few examples of substances expressed in plants that would not be considered plant regulators and therefore not under EPA's authority are: (1) Substances intended to alter the nutritional composition of the plant; (2) substances intended to enhance the plant's resistance to chemical herbicides; and (3) substances intended to alter the flavor or the texture of the food.

V. Regulatory Process Under FIFRA and FFDCA

This section outlines the process EPA proposes to follow for plant-pesticides subject to FIFRA and/or FFDCA requirements. It describes the options that EPA is evaluating for its approach to the regulation of testing of plant-pesticides and includes current proposed Agency's thinking for sale or distribution of a plant-pesticide. In the future, EPA will propose regulations concerning the procedures for plant-pesticides under FIFRA (e.g., EUPs and labeling).

In the period before procedures that are specific for plant-pesticides are finalized, existing regulations (e.g., 40 CFR parts 156, 158, and 172) will be used as the basis for plant-pesticide regulatory procedures. However, the Agency is aware that many of these existing procedures may not be appropriate for plant-pesticides, and encourages producers to contact EPA on a case-by-case basis.

Producers of plant-pesticides should be aware that having no obligations under one of the statutes (FIFRA or FFDCA) does not necessarily mean that there are no obligations under the other statute. Producers should therefore evaluate the requirements of both

statutes before reaching a determination on their responsibilities.

Producers should also be aware that if certain plant-pesticides present unreasonable risk and there are limited or no risk mitigation options available to the Agency for certain plant-pesticides submitted for registration, the Agency would not be able to register the plant-pesticides. Potential registrants are again encouraged to consult with EPA for guidance early in the product development cycle.

4. *Testing of Plant-pesticides*

The following unit outlines EPA's preferred approach to when a producer would contact EPA under FIFRA and FFDCA during testing of a plant-pesticide. The procedures are laid out in terms of whether the crop would be used as food and/or feed since this question is among the first considerations in determining when to contact EPA.

1. *Food and/or feed use.* This unit gives guidance as to when a producer would have obligations under FFDCA and FIFRA if a plant-pesticide is tested in a crop/plant used for food and/or feed or if any adjacent food/feed plants would produce the plant-pesticide.

a. *FFDCA requirements.* The FFDCA requirements for a plant-pesticide would be based on the following considerations.

(i) *Existing exemption from the requirement of a tolerance.* If there is an existing exemption from the requirement of a tolerance for the plant-pesticide in the crop/plant to be tested (e.g., if EPA's proposed tolerance exemptions published elsewhere in todays issue of the Federal Register), there would be no further obligations under FFDCA.

(ii) *Containment.* A tolerance review would not be required for the test if the crops/plants containing the plant-pesticide are tested in a way that ensures adequate containment within the test site of the genetic material necessary for the production of the pesticidal substance. "Adequate containment" in this context would include ensuring any adjacent crops, to be used as food, do not express the plant-pesticide as a result of successful pollination by the plant used to test the plant-pesticide.

(iii) *Crop destruct.* A tolerance review would not be required for the test if all crops within the test site are destroyed or used for experimental purposes only.

(iv) *Petition for temporary tolerance or exemption.* If there is no existing exemption from the requirement of a tolerance for the plant-pesticide, if containment is not adequate or the crop is not destroyed, a petition for a temporary tolerance, a full tolerance, or an exemption from the requirement of a tolerance must be submitted to the Agency, as described at 40 CFR 180.7 and 180.31. Such a crop cannot be sold or distributed for use as food or feed unless a tolerance or exemption from the requirement of a tolerance has been obtained for the plant-pesticide in that crop and the plant-pesticide residues fall within the tolerance limits.

b. *FIFRA requirements.* Prior to registration, if a plant- pesticide is produced in a crop/plant that is to be used as food or feed (condition (iv) above) at any field test acreage, producers would apply for an Experimental Use Permit (EUP) for that plant-pesticide under FIFRA.

2. *Nonfood and nonfeed use.* This unit describes when a producer would have obligations under FFDCA and FIFRA if the plant-pesticide is used in a crop or plant that will not be used for food and/or feed.

a. *FFDCA requirements.* If a plant-pesticide is produced in a crop/plant that will not be used as food and/or feed, there would be no requirements under FFDCA as long as the genetic material is adequately contained to avoid successful transfer and expression of the plant-pesticide in adjacent crops. (Refer to Unit V.A.1.a.(ii) and (iii). above for conditions of containment and crop destruction under which there are no FFDCA requirements.)

b. *FIFRA requirements.* If a plant-pesticide is produced in a crop/plant that will not be used as food and/or feed, an Experimental Use Permit would be required under the following conditions.

(i) *Not subject to the Plant Pest Act.* If a plant-pesticide is produced in a plant that is not subject to the authority of the Plant Pest Act, an EUP would be required at first field introduction. This EUP requirement would extend to plant-pesticides in plants that are not within the statutory jurisdiction of the Plant Pest Act, including those for which APHIS has made a determination of nonregulated article status (58 FR 17044).

(ii) *Acreage requirements for plant-pesticides in plants subject to the Plant Pest Act.* For plant-pesticides produced in plants that are (1) subject to the authority of the Plant Pest Act and (2) not used as food or feed, an EUP would be required when one of the following two conditions is met.

(A) *Acreage limit for individual field test.* An EUP generally would be required if an individual field test for a plant-pesticide in a particular crop will be on greater than 10 acres of land. Once a requirement for an EUP has been triggered, if there are other field test site locations, for that plant-pesticide, of less than 10 acres that would also be planted in the same year, they would be included in the EUP. If a field test site of greater than 10 acres is planted for a crop that is producing more than one plant-pesticide, all field test sites for each of the plant-pesticides would be included in the EUP if these field tests would occur in the same year.

(B) *Upper cumulative acreage limit for field tests.* Notwithstanding (A) above, an EUP would be required if the cumulative acreage of all field tests for the plant-pesticide in a particular crop exceeds 50 acres of land regardless of the acreage of individual field sites.

(iii) *Other conditions for EUPs.* The Agency could grant multi-year EUPs for plant-pesticides under certain conditions. For example, a multi-year EUP could be appropriate if the acreage of the field sites will increase yearly but the field test design and containment measures for the field sites remain the same such that there is not an increased risk for nontarget effects or outcrossing. In addition, producers should be aware that the data requirements for an EUP may not be different from the data requirements for a registration of the plant-pesticide (see Unit VI. of this document).

B. Sale or Distribution

1. *FFDCA.* If a plant-pesticide is produced in a crop to be sold or distributed as food and/or feed and is not already exempt from the requirement of a tolerance, the Agency must establish a tolerance or exemption from the requirement of a tolerance before sale or distribution.

2. *FIFRA.* Before sale or distribution of a plant-pesticide, a producer would have to obtain a registration for the plant-pesticide product, unless it is otherwise exempt, as described in this document (Unit VI.B. of this document). The plant-pesticide product consists of the active ingredients and inert ingredients, as defined in Unit IV.B. of this document, EPA anticipates that the plant-pesticide product would be registered for use in a particular plant or crop (e.g., field corn). While the Agency anticipates that most registrations of plant-pesticides would be for use in a particular plant or crop, there may be instances where a registration of a plant-pesticide could be limited to a particular variety or be restricted in some other way if risk considerations warrant such a restriction.

In terms of shipping, EPA does not intend to change the status of the exemption under section 12(b)(5) of

FIFRA which allows the shipping of a pesticidal substance under the conditions of section 12(b)(5) without being subject to penalty for failure to have a registration or EUP.

C. Agency Considerations Underlying Regulatory Procedures and Alternative Approaches for Testing of Plant-pesticides

1. *Agency considerations underlying FFDCA regulatory procedures.* Under FFDCA at the field testing stage, the Agency will generally treat plant-pesticides as it treats other pesticides in terms of when EPA regulatory oversight begins. Thus, producers will be subject to FFDCA requirements when the crop plant containing the plant-pesticide is to be used as food or feed. EPA recognizes that many of its requirements for addressing feed under FFDCA arise because some pesticidal substances may be metabolized or stored by domesticated animals in ways that expose humans to these pesticides and/or their residues through consumption of meat or other animal products (e.g., milk and eggs). EPA also recognizes that the possibility that consumers might be exposed to proteinaceous plant-pesticides through such animal products is extremely low. Proteinaceous plant-pesticides are likely to be composed of the same constituents as animal protein or other animal cellular components, and, thus, would readily enter the metabolic cycles of the animal cell. For proteins, it is not anticipated that recalcitrant residues will be generated or accumulated in animals used as sources of meat. However, EPA cannot predict that all plant-pesticides will behave as proteinaceous plant-pesticides. Thus, EPA will require plant-pesticides to be subject to FFDCA when the plants producing the plant-pesticide are used as feed. Data requirements associated with the tolerance review will, however, be imposed recognizing the characteristics of proteinaceous plant-pesticides.

2. *Agency considerations underlying FIFRA regulatory procedures.* The following unit describes EPA's rationale for its preferred trigger for EUP's and describes alternative approaches to the EUP trigger EPA is considering. The preferred approach and the alternative approaches address testing of plant-pesticides that are subject to the Plant Pest Act and are not used as food and/or feed (conditions described in Unit V.A.2.b.ii. of this document).

EPA believes some type of oversight of plant-pesticides at the field testing stage is appropriate. Plant-pesticides are, by definition, part of a living organism. Thus, plant-pesticides present unique mechanisms by which they can be produced and spread in the environment. Because of the different risk considerations and risk mitigation measures associated with plant-pesticides than with traditional chemical pesticides, EPA is examining whether the 10 cumulative acre presumption in 40 CFR 172.3 is appropriate with regard to plant-pesticides.

Potential risks associated with tests of plant-pesticides will depend upon a number of variables, including the size of the test plot, the biology of the plant and the properties of the pesticidal substance. At smaller acreages, tests of plant-pesticides can usually be designed with containment that is adequate to minimize the spread of the plants' genetic material beyond the test site, thereby limiting the spread of the active ingredient from the field test site. Successful containment of the genetic material would result in minimal exposure of humans and other nontarget organisms to the active ingredient beyond the test site.

During the development of plant-pesticides, depending upon the biology of the plant tested and the location of the field test sites, there will be a point at which it will be impractical to try to contain the spread of the genetic material. In terms of risk, the Agency believes its oversight of plant-pesticides under FIFRA should begin at the point when containment is impractical and the potential for significant exposure to nontarget organisms begins to increase.

As tests of plant-pesticides progress to larger acreages, the potential hazards to nontarget organisms will generally be increased because of the potential for significant exposure to nontarget organisms on the test site. In addition, lack of adequate containment may mean the spread of the active ingredient and subsequent possible environmental exposure beyond the test site. Moreover, if the active ingredient is spread to neighboring crops used for food and/or feed, human dietary exposure could occur.

Under any of the options put forth by EPA for EUP thresholds for plant-pesticides, EPA would retain the authority to rebut the presumption that an EUP is not required for certain small-scale testing. Such a rebuttal would be based on risk/benefit considerations. Thus, EPA may, on a case-by-case basis require EUP's for testing conducted with plant-pesticides at acreages smaller than those described in the options. EPA does not anticipate requiring EUP's at acreages below the threshold triggering EUP requirements (regardless of which option is chosen) very often, and when EPA determines that such an EUP is warranted, EPA will provide notice to the producer of the plant-pesticide being tested.

In addition to risks in terms of hazard and exposure, EPA considered the following in developing its options for the threshold for EUPs for plant-pesticides: (1) Differences in the traits of plant-pesticides (e.g., the delivery system of the pesticide in that plant-pesticides are produced and used in a living plant) in comparison to more traditional chemical pesticides (e.g., they are applied to a plant); (2) varietal development procedures used in the plant breeding industry and the impact this has on the design of field testing; (3) USDA's activities under the Plant Pest Act for transgenic plants (some of which will be engineered to express plant-pesticides); (4) clarity to the regulated and other communities; (5) EPA's traditional approach to oversight of field testing in terms of establishing acreage cutoffs so as to provide regulatory consistency; and (6) costs to potential registrants and efficient utilization of Agency resources.

a. *EPA's preferred approach: single-site acreage threshold.* Under its preferred approach, the Agency would use the concept that larger acreage for individual field sites leads, in general, to greater exposures and greater potential for escape from biological containment. Therefore, the Agency would link the concept of greater exposure to an acreage cutoff (i.e., 10 acres for a single field test site, 50 cumulative acres; see Unit V.A.2.b.ii of this document). EPA recognizes that the acreage cutoff in its preferred approach may be more closely correlated with the potential for larger exposures for some crops than for others. However, it believes that the advantage of clarity and predictability associated with the acreage cutoff would outweigh this disadvantage. In addition, EPA would put an upper limit on the number of cumulative acres that could be planted without an EUP because multiple sites of larger acreages would lead to an increased potential for exposure to nontarget organisms on the cumulative acreage.

b. *Alternative approaches for testing of plant-pesticides.* EPA is also considering four alternative approaches to triggers for Agency oversight for testing of plant-pesticides, under FIFRA section 5, for plant-pesticides that are subject to the Plant Pest Act and are not used as food/feed.

(i) *Containment as trigger for EUP.* EPA seriously considered, and may yet choose to use as its trigger for EUP

requirements, the concept of containment. Essentially, once a plant can no longer be effectively isolated biologically, EPA's EUP requirements would be triggered. To be isolated biologically means that the genetic material of the plants on the test site does not have a significant potential for successfully spreading to neighboring plants (including neighboring crop plants) through sexual recombination. The concept of biological isolation is basic to USDA's approach and use of such a standard by both agencies could permit a smooth transfer of oversight for plant-pesticides from USDA to EPA. The disadvantage of using this approach for EPA and for potential registrants, is that what constitutes "appropriate containment" varies from crop to crop and test to test. EPA is concerned that the lack of a clear line as a standard may result in numerous consultations between EPA and potential registrants over what constitutes appropriate containment. In addition, other groups, such as the public and public interest groups, may not be able to readily determine whether a potential registrant is in compliance with EPA requirements. Finally, there are exposure issues (i.e., larger potential for exposure on individual field sites at larger acreages) that are not addressed by this alternative.

(ii) *USDA/APHIS determination of nonregulated status as trigger for EUP.* A second alternative approach EPA is considering is based on USDA's determination of nonregulated article status (58 FR 17044). Under this alternative, producers would apply to EPA for an EUP (or registration) at the time that they apply to APHIS for a determination of nonregulated article status. Although this approach could potentially minimize duplicative efforts by the two agencies, it lacks regulatory clarity and consistency as to when a producer would have to comply with EPA requirements. This approach may result in producers being uncertain as to when they should contact EPA. The result of this lack of regulatory clarity could be producers applying to EPA too late in their product development cycle.

(iii) *Cumulative acreage in a single state as trigger for EUP.* The third alternative would be based on an acreage trigger, as is EPA's preferred approach. Under this approach, an EUP would be required when the cumulative acreage in any one state exceeds 10 acres. This alternative would allow producers to test a plant-pesticide in a number of different locales yet limit exposure to the plant-pesticide in any one locale. However, this approach also lacks regulatory clarity as to when producers must contact EPA if a number of different states are involved. Other groups, such as the public and public interest groups may not be able to readily determine whether a producer is in compliance with EPA requirements. In addition, fairly large total acreages of testing might occur since up to 10 acres could be tested in each of 50 states. The potential for exposure to nontarget organisms and outcrossing to wild relatives could be greater with this alternative than for the preferred or other alternative approaches.

(iv) *Cumulative acreage as trigger for EUP.* A fourth alternative EPA is considering is to utilize for plant-pesticides the acreage presumption in the current EUP regulations; i.e., an EUP is presumed not to be required at less than 10 cumulative acres of land. The advantage this alternative presents is consistency in EPA's EUP regulations for all pesticides. The disadvantages to this approach are that it may not correlate well with current plant breeding procedures (varietal testing) that can require a number of field sites of smaller acreages and it may result in more duplicative efforts by EPA and USDA.

It should be noted that EPA has not addressed in this document how it will approach aquatic testing of plant-pesticides. Producers anticipating research and commercialization activities with aquatic plants are encouraged to contact the Agency.

D. Labeling Requirements under FIFRA

Labeling is required for pesticides that are regulated by EPA under FIFRA. Labeling includes both written material accompanying the pesticide and labels on or attached to the pesticide, its container, or wrapper. Labeling thus may have different forms. A pesticide which does not meet labeling requirements is considered to be misbranded and enforcement action can be taken.

The Agency recognizes that certain types of labeling which are appropriate for chemical pesticides will not be practical for plant-pesticides. For example, it would be impractical to require labels to be physically attached to the plant-pesticide itself (i.e., the pesticidal substance and the genetic material necessary for the production of the substance) at any point in the regulatory process (i.e., EUPs or registration). Therefore, the Agency is considering the types of labeling that would be appropriate for plant-pesticides during testing and at the time of registration.

Labeling can include both prescriptive and informational components. The Agency is considering utilizing both these types of labeling for plant-pesticides. For example, plant-pesticides that are regulated by EPA but are not yet registered (e.g., are under an EUP) may have prescriptive labeling that would set forth the appropriate conditions for field testing, such as geographic location, field test design, and other limitations. The Agency believes that this type of labeling would be appropriate at this point in the regulatory process because the Agency would not have yet made a determination that the plant-pesticide generally will not result in "unreasonable adverse effects" without the restrictions specified on the label. Thus, the prescriptive labeling would be necessary to assure there would not be unreasonable adverse effects during the test of the plant-pesticide.

Plant-pesticides that are registered would also have prescriptive labeling that would accompany the plant-pesticide throughout the process of developing and producing the commercial plant variety that contains the plant-pesticide. Such prescriptive labeling would, for example, specify the EPA registration number, the ingredient statement, and the plants/crops in which the plant-pesticide may be produced. It is unlikely, however, to include many of the limitations, discussed above, likely to be used for unregistered plant-pesticides because these types of limitations would not be practical for registered plant-pesticides. For example, limitations such as conditions for planting, field design, or certain geographical restrictions may not be practical given the nature of the use and distribution patterns of the plants that produce the plant-pesticide (e.g., farmers saving seed for replanting, the potential for spread of the plants' genetic material). In some cases it will be appropriate for the Agency to assume that, at sale or distribution, the plant-pesticide will be introduced into all plants/crops (and their varieties) that are included in the plant-pesticide registration (e.g., all corn varieties). The appropriateness of this assumption will be considered, on a case-by-case basis, by EPA in its assessment of whether a plant-pesticide produced in a particular crop/plant presents "no unreasonable adverse effects."

The prescriptive label for a registered plant-pesticide may include a provision requiring informational labeling on plants/seeds containing the plant-pesticide to give information or notice to farmers and growers of the plant-pesticide. For example, informational labeling of this type could be attached to bags of seeds and could inform

farmers of the type of pesticide that the plants will produce and against which pest it is active. EPA believes that such informational labeling will help to prevent unnecessary application of additional pesticides to the plants. The prescriptive label may require that the informational labeling accompanying plants or seeds bear other necessary statements. For example, the informational label could be required to have a statement that informs farmers and growers that they should report any adverse effects to the registrant through an address or telephone number provided on the label.

E. Import/Export of Plant-pesticides

Unregistered, exported plant-pesticides that are not exempt from FIFRA regulation will be subject to the Final Export Policy Statement; Rule (40 CFR parts 168 and 169, 58 FR 9062). However, the Agency recognizes that some of the labeling requirements for exports may not be applicable to plant-pesticides (e.g., net weight of the plant-pesticide may be difficult to determine in some cases). EPA is also considering whether to require an informational label on exported seeds/plants containing a registered plant-pesticide that contains: (1) Information about the type of plant-pesticide produced by the plants and the target pest, and (2) a statement that EPA's determination for registration of the plant-pesticide is based solely on consideration of risks in the United States and that this determination does not extend to use in other countries.

If an imported plant-pesticide will be used for pesticidal purposes (e.g., if the seeds are sold to be planted and the resulting plants are intended to produce the plant-pesticide), the producer must apply for a registration of the plant-pesticide under FIFRA. As with labeling for exports, certain provisions in the "Notice of Arrival of Pesticides and Devices" (EPA form 3540–1) may not be applicable to plant-pesticides. If a producer plans to import seeds/plants that contain a plant-pesticide, a tolerance or exemption from the requirement of a tolerance must be obtained if the plants/seeds will be used for food and/or feed. The Agency encourages producers to contact EPA with questions concerning procedures for both import and export of plant-pesticides.

VI. Information Needs Under FIFRA and FFDCA

A. Introduction

This unit describes the types of information EPA would need, in general, to evaluate a plant-pesticide during product development and before the pesticide could be registered for sale or distribution. The types of information the Agency would need for its evaluation of a plant-pesticide will depend upon a number of variables, including the biology of the plant and the properties of the pesticidal substance. The specifics of EPA's evaluation of testing of a plant-pesticide (e.g., evaluation of containment) will also depend, to a certain extent, on which of the options for EUP triggers apply in a final policy statement (i.e., the time during product development that a producer is required to contact the Agency varies depending on the option selected (see Unit V. of this document).

This unit is designed to give general guidance while maintaining an appropriate flexibility to data needs for individual cases. It covers the areas of product analysis, environmental fate, ecological effects, and human health effects. Producers are encouraged to consult with the Agency on the types of information relevant to EPA's evaluation of their particular product.

Although plant-pesticides present new considerations for risk assessment, the framework that is used to evaluate risks for chemical and biological pesticides can be used as a model if the unique aspects of the plant-pesticides are taken into account. The major characteristic of plant-pesticides that is different from traditional pesticides is that the plant itself produces the pesticidal substance rather than the pesticide being applied to the plant.

Thus, the exposure pattern may be very different for plant-pesticides than for traditional pesticides, both because of how the pesticide is produced and the biology of plants. This different exposure pattern has implications for the evaluation of field tests (e.g., the analysis of containment of the test) and for exposures resulting from sale or distribution. In turn, the unique exposure potential may involve different non-target or endangered species than for a traditional pesticide. However, the potential for causing adverse health effects may be more circumscribed than for traditional pesticides because, in many cases, the only significant route of human exposure may be oral.

B. General Considerations for Product Development and Sale or Distribution

1. *Product development.* As a plant-pesticide product is developed, it is usually necessary to test, in the field, plants producing the pesticide. At this point, EPA may not have extensive information on ecological and human health effects for these products. Unreasonable adverse effects associated with field tests can be minimized by conducting these tests under conditions appropriate to ensure containment. Adequate containment would ensure that exposure of humans and nontarget organisms to the active ingredient beyond the field test site is minimal. Thus, for field testing during product development the Agency would need information to determine whether containment is sufficient. If containment is not sufficient, information to determine the potential effects of the uncontained testing would be needed.

Any human dietary exposure will require a tolerance, or exemption from requirement for a tolerance, regardless of the stage of product development or the size of the field tests. Even if the crop is destroyed, a tolerance, or exemption from requirement for a tolerance, may be necessary if there is genetic outcrossing to other crops that would be used as food or feed (See Unit V. of this document). Information addressing health effects thus may be necessary to allow a tolerance assessment.

2. *Sale or distribution.* In order to assess the potential exposure when a plant-pesticide is sold or distributed, EPA will consider whether all varieties of a crop in which the plant-pesticide is registered (see Unit V.B. of this document) will be able to express the pesticidal substance. Potential exposure could also result if the plant-pesticide is expressed by plant relatives to which the genetic material encoding the plant-pesticide could be transferred. This analysis of exposure is a component in the possible identification of the types of nontarget organisms that associate with particular types of crops/plants and therefore may be exposed to the pesticidal substance. This type of analysis would be considered depending on the plant-pesticide/plant combination. In addition, sale or distribution will often involve human dietary exposure and may thus require information to address those risks and to support a tolerance or tolerance exemption.

C. Product Analysis

Product analysis/characterization data and information are critical for assessing potential risks to humans and the environment. Product characterization embraces five basic areas: (1) Identification of the donor organisms and the nucleotide sequences that are inserted into the recipient plant; (2) identification and description of the

vector or delivery system used to move the nucleotide sequences into the recipient plant; (3) identification of the recipient organism, including information on the insertion of the nucleotide sequences (e.g., stability of insertion); (4) chemical characterization of the plant pesticide products; and (5) data and information on the levels of the pesticidal substances in the recipient plant, including any tissue specificity of expression.

D. Environmental Fate Analysis

1. *Environmental fate risk issues.* An accurate assessment of the fate, transport, and persistence of the pesticidal gene product (pesticidal substance) in the environment is essential to the entire risk assessment process. This information will determine if there is adequate containment during product development and will support the ecological non-target species and the health effects risk assessments for sale or distribution of the products. The following environmental fate risk issues are associated with field tests and sale or distribution of a plant-pesticide:

(1) Increasing the ability of the modified plant to survive outside of cultivation through the introduction of a specific trait.

(2) Gene capture and expression of the introduced trait by a wild or weedy relative.

(3) Potential for a trait conferring a selective advantage to a plant in a natural plant community with the result of increasing the "weediness" of that species.

(4) Environmental fate of the pesticidal substance. The dosage to soils after plant senescence and incorporation into the soil, rate of degradation or dissipation and transport in the environment. Also whether or not the pesticidal substance is either exuded or volatilized from the plant during the growing season, resulting in a continuous application to the environment.

The environmental fate of plant-pesticides introduced into the environment is composed of two facets: the movement of the gene encoding for the pesticidal substance (biological fate) and the fate of the pesticidal substance itself (chemical fate). Some of the information about the biology of the plant producing the plant-pesticide may be available in the published literature and this information should be used to address the biological fate risk issues. There are several points of information that a producer should consider when developing a plant-pesticide for sale or distribution in agriculture. These points of information are presented in the Units VI.D.2. through VI.D.4. of this document. The points are arranged in a tiered framework that allows for resolution of the risk issue as early as possible in the review process.

2. *Biological fate analysis.* The first consideration in the biological fate analysis is whether or not the plant producing the plant-pesticide can exist under other than cultivated conditions. This consideration results from risk issue (1) in Unit V.D.1. above.

The next consideration is whether or not the plant producing the plant-pesticide has weedy or wild relatives and whether the relatives are distributed in or near the areas where the plant will be grown. This consideration results from risk issue (2) in Unit VI.D.1. above. If the plant producing the plant-pesticide does have weedy or wild relatives of concern, the next consideration is whether, based on its life cycle, pollinator requirements, and genetic limitations, it can take part in a successful outcrossing event.

If the plant producing the plant-pesticide has the ability to outcross, the next considerations are its outcrossing rate and pollen longevity under laboratory conditions. If it is determined that either or both of these factors are high, outcrossing rates should be determined under field conditions. This consideration addresses risk issue (2) in Unit VI.D.1. above.

If significant outcrossing is achieved under field conditions a determination of whether the plant-pesticide confers a selective advantage to the relative would be made. This consideration addresses risk issue (3) in Unit VI.D.1. above.

3. *Exposure to the pesticidal substance produced by the plant.* If there is a toxicological concern for the plant pesticidal substance, an assessment of expression levels in all or some parts of the plant may be required. This consideration addresses risk issue (4) in Unit VI.D.1. above.

4. *Chemical fate analysis.* Determining the persistence and movement of the pesticidal substance in the environment would be required if there is a toxicological concern for that pesticidal substance. Points that should be considered are the pesticidal substance's persistence and mobility in all environmental media (soil, water, and air). If the substance is persistent and another crop is grown in rotation with the transformed crop, a crop rotation study would be required. Similarly, if the pesticidal substance is stable in the environment and is expected to reach aquatic environments, a fish accumulation study would be required. This consideration addresses risk issue (4) in Unit VI.D.1. above.

E. Ecological Effects

Sale or distribution of a plant-pesticide may ultimately lead to the plant-pesticide being expressed in the entire agricultural crop of the plant that is producing the plant-pesticide and in any other crops and/or relatives with which the plant can cross-breed. A careful analysis of all potential nontarget species (including threatened or endangered species) that may be susceptible to the pesticidal substance may thus be needed. Some plant/plant-pesticide combinations may not be acceptable for registration if use could be expected to result in unreasonable environmental effects if traditional risk mitigation restrictions are not appropriate for the plant-pesticide. In these cases, genetic limitations on the expression of the pesticidal substance in plants, or on the potential for gene transfer to other plants, may result in sufficient risk reduction to allow registration. Also, if the presence of the plant-pesticide is limited to the actual plant material, the number and kinds of species exposed may also be limited.

EPA has, for traditional pesticides, relied on single species testing to evaluate potential effects on nontarget species, and this approach will continue to be of value. However, the standard test species and the standard acute exposure protocols used for chemical pesticides may not be sufficient to evaluate plant-pesticides due to their unique exposure scenario, e.g., the presence of the pesticidal substance as part of the plant and the potential for gene flow to other plants.

In addition, the substance to be tested (whole plants, extracts of plants, pure pesticidal-substance, etc.) may have to be determined on a case-by-case basis, but the substance should be tested in an ecologically relevant manner. Unlike traditional chemical pesticides where direct contact is the predominant form of exposure, exposure to plant-pesticides will primarily be from ingestion of, or contact with, plant tissues that contain plant-pesticides.

Traditional test protocols rely on a maximum-hazard dose to ensure that potential adverse effects are detected. However, it may be difficult to obtain a maximum-hazard dose using plant-pesticide materials if there are low expression levels of the pesticidal substance in the plant. Therefore, in some cases, chronic exposure testing may be more appropriate.

The following points may be of particular value in performing an ecological risk assessment:

(1) An analysis of which non-target species feed on, or contact, plant parts that will contain the pesticidal substance will be particularly helpful in identifying the species to be tested. Consideration should be given to which species are most representative of those likely exposed to the plant-pesticide.

(2) If the pollen of a plant contains the pesticidal substance, the pesticide substance may be airborne beyond the immediate field location. The effect on aquatic invertebrates may need to be determined. Plant pollen enters the aquatic environment quite readily through wind movement. In addition, honeybees, and particularly honeybee larvae, are likely to be exposed to pollen. Honeybee larvae may be susceptible to these plant-pesticides, especially those intended to control insect larvae, even if the adult honeybees are resistant.

(3) If the pesticidal substance is expressed in the seed or fruit, a different range of non-target organisms will be exposed than if the pesticidal substance is produced in the pollen. In this instance, possible effects on birds and mammals should be considered.

(4) The duration of testing is a factor. If the pesticidal substance is expressed by the plant throughout the entire plant life-cycle, some nontarget species may be exposed to a chronic dose of the substance as compared to traditional pesticide usage which often results in an acute dose. Chronic exposure in terms of the duration of expression of the plant-pesticide by the plant could be measured in terms relative to the life cycles of nontarget organisms likely to be exposed.

(5) If, after harvest at the end of the growing season, the plant tissue containing the plant-pesticide is tilled into the soil or left in the field to decompose, soil organisms (i.e., Colembola and other soil arthropods, nematodes, mollusks, and annelids) may receive a low level chronic exposure, depending on the stability of the pesticidal substance. This may affect decomposition processes which occur naturally in the soil.

(6) Threatened or endangered species may be at risk from widespread or uncontained use of the plant-pesticide. Since the pesticidal substance may have the potential to be expressed in the entire crop and related plants, it may be difficult to limit the exposure of threatened or endangered species. There is particular cause for concern if there are any threatened or endangered species related to the target species that feed on the plants or if there are any threatened or endangered species related to species susceptible to the pesticidal substance. Information on the feeding habits and preferred food sources of any potentially affected threatened or endangered species will be needed to address this issue.

(7) Secondary feeding effects may increase the possibility of non-target exposure, e.g., the possibility that species feeding on the plant would accumulate enough pesticide to affect predatory species feeding on them.

(8) The possibility of transfer of a disease- or insect- resistant trait to wild or weedy relatives or the presence of the trait in the crop, itself, may create a weed or may increase the competitiveness of a known weed. There may be cause for concern if related, naturally-occurring, pest-resistant plants are weeds, particularly if this particular pest-resistant trait is found in the most aggressive varieties of the weeds. If the pesticidal trait results in significantly greater pest-resistance, analysis of the competitiveness with naturally occurring weeds may be a practical way to address this issue.

F. Human Health Affects

Plant-pesticides are likely to present a limited exposure of the pesticidal substance to humans. In most cases, the predominant, if not the only, exposure route of concern will be dietary. Significant respiratory and dermal exposures would be unlikely. A full assessment to be made from a specific, limited, data set (as compared to traditional pesticides) can thus be made. Information on the presence of the pesticidal substance in edible portions of the crop will help determine the degree of human dietary exposure. In cases where the plant-pesticide containing crop is used as animal feed, domestic animal safety information may be necessary.

The types and numbers of mammalian toxicology studies needed for human health effects risk assessment will depend on whether the plant pesticide is a protein; and, if not, whether the plant pesticide is analogous to a traditional chemical pesticide or a biochemical pesticide.

For plant-pesticides that are proteins, an acute oral toxicity study in the rodent may be sufficient to address health issues and/or questions. Although not yet validated, an *in vitro* digestibility assay may answer questions about allergenicity or about the potential for toxicity of proteins including those with a deliberately altered amino acid sequence.

Naturally occurring non-proteinaceous plant pesticides with a non-toxic mode of action against the target pest could be addressed in a manner analogous to biochemical pesticides (although the Agency is proposing to exempt this category of plant-pesticide under FIFRA, they would not necessarily be exempt under FFDCA). Non-proteinaceous plant-pesticides with a toxic mode of action could be addressed as for traditional chemical pesticides. The focus on data requirements for non-proteinaceous plant-pesticides will also primarily be on the oral route of exposure.

G. Development of Resistance to Plant-pesticides

EPA recognizes that there is a potential for the development of resistance to plant-pesticides. At present, the issue has been raised particularly in the case of the *Bacillus thuringiensis* insecticidal delta-endotoxin. Field resistance to the delta-endotoxin has been documented for foliar applications of the microbial pesticide, *Bacillus thuringiensis* (Ref. 7). It is postulated that resistance to the delta-endotoxin could develop when it is produced by plants. The development of insect resistance to the delta-endotoxin could lead to a loss in the effectiveness of this valuable pesticide. EPA is committed to the development of pesticides that are viable alternatives to more toxic and persistent chemical pesticides. The Agency is considering how it can best encourage the development of agricultural practices that will minimize the development of resistance to plant-pesticides. Toward this end, the Agency has begun to analyze the regulatory and nonregulatory tools it could use to address resistance to all pesticides, including plant-pesticides.

VII. Interactions With Other Agencies

EPA is the Federal agency primarily responsible for the regulation of pesticides. However, in fulfilling this mission EPA works closely with the U.S. Department of Agriculture (USDA) which has responsibilities under the Plant Pest Act and the Plant Quarantine Act and the U.S. Food and Drug Administration (FDA) which has responsibilities under FFDCA.

A. USDA

USDA has authority to prevent the introduction and dissemination of plant pests under the Plant Pest Act and the Plant Quarantine Act. An introduction at any acreage of a plant that is under the jurisdiction of the Plant Pest Act requires either that a permit be obtained from USDA's Animal and Plant Health Inspection Service (USDA/APHIS) or for certain plants that a notification be submitted to USDA/APHIS, unless it

has been exempted from those requirements.

EPA and USDA/APHIS have consulted and exchanged information on plants and plant-pesticides and intend to continue to do so in the coordination of their regulatory activities. The two agencies also have and intend to continue to consult closely on scientific issues related to the safety considerations associated with the environmental impact of field tests of plant-pesticides.

B. FDA

Pursuant to FFDCA and the reorganization that created EPA, pesticides as defined by FIFRA are subject to EPA's regulatory authority under FFDCA. However, FDA's authority under FFDCA extends to any nonpesticidal substance that may be introduced into a new plant variety and that is expected to become a component of food.

FDA and EPA have and intend to continue to consult closely on any jurisdictional questions, as well as on scientific matters where consultation will be helpful in resolving safety questions. Both agencies agree that EPA will address under its regulatory jurisdiction the food safety issues associated with the plant-pesticide, including marker genes used to confirm the presence of the DNA necessary for the production of the pesticidal substance. Any food safety questions beyond those associated with the plant-pesticide, such as those involving changes to food quality or raised by unexpected or unintended compositional changes, are under FDA's jurisdiction (Ref. 3). Similarly, food safety issues associated with alterations in levels of a substance with pesticidal properties, or the appearance of a substance with pesticidal properties, that occur as an unintended consequence of modifications to a non-pesticidal trait would also fall under FDA's authority..

VIII. External Review

In developing its approach to regulating plant-pesticides, EPA has requested the advice of two scientific advisory committees in three meetings. On December 19, 1992, pursuant to section 25 of FIFRA, a Subpanel of the FIFRA SAP was convened to review a draft policy statement on plant-pesticides and respond to a series of scientific questions posed by the Agency primarily on EPA's approach under FIFRA. On July 13, 1993, a Subcommittee of the EPA Biotechnology Science Advisory Committee (BSAC) was convened to address a series of scientific questions primarily on EPA's approach under FFDCA. On January 21, 1994, a joint meeting of the SAP/BSAC Subpanel on plant-pesticides was held. The issues raised at these meetings are discussed below, together with the Agency's response. (Full reports from these meetings are available in the public docket.)

A. Substances New to the Plant

Questions on how best to describe "substances that are new to the plant" were posed at all three science advisory meetings. At its December 1992 meeting, the FIFRA Subpanel was asked whether the taxonomic demarcation of "genus" was appropriate, or whether some other demarcation would be more appropriate. The Subpanel expressed concern over an exemption based on a taxonomic definition and suggested the Agency evaluate a series of considerations involving the potential for quantitative and qualitative differences in exposure to a plant-pesticide.

The SAP Subpanel suggested that the Agency would "need to create a workable balance between effective regulatory oversight and encouragement of the development of plant-produced pesticides."

At its July 13, 1993 meeting, the BSAC Subcommittee addressed a related issue with regard to the regulation of plant-pesticides under the FFDCA and human dietary exposures to plant pesticides.

Included in questions to the Subcommittee were queries on the availability of information on current levels of exposure in the diet to plant-pesticides in raw agricultural commodities and on which plant-pesticides might be of concern should their levels be significantly increased.

The BSAC Subcommittee in their report stated that no formal, complete data base for such information exists. Rather most of this knowledge is part of breeders' experience, with breeders depending primarily on familiarity with food crops (e.g., knowledge of which crop plants have the ability to produce which toxicants) to ensure consumers are not exposed to deleterious levels of such substances. In general, little information exists on the range of levels of plant-pesticides in plants, including ranges within the most studied grouping, food plants. The mechanisms through which plants display resistance to pests, moreover, have not been worked out very well. Based on experience, however, the BSAC Subcommittee suggested EPA consider a scheme based on sexual compatibility to identify those groupings wherein plant-pesticides might present new and novel dietary exposures and those that would not.

The use of sexual compatibility and/or taxonomy as a standard for the potential for significantly different environmental exposures was discussed at the January 21, 1994, joint SAP/BSAC Subpanel meeting. The joint Subpanel members were supplied with the reports of the previous meetings and drafts of proposals analyzing the strengths and weaknesses of approaches based on sexual compatibility and/or taxonomy. In response to the question of whether plants in a sexually compatible population are likely to share substances or traits, the joint Subpanel agreed that sexually compatible plants are more likely to have a common constitution than unrelated plants and thus are less likely to lead to novel exposures.

The report of the January 21, 1994, joint SAP/BSAC Subpanel meeting, indicates that the joint Subpanel agrees that both the concept of sexual compatibility and the concept of taxonomy should restrict the occurrence of significantly different exposures and finds that Option 3 is a reasonable approach for agricultural plants. However, the Subpanel questioned whether under the taxonomic criterion of Option 3 (and Option 2) a low probability of novel exposures can be extended to wild or semi-wild plants. For these types of plants, the genus standard may result in the exemption from regulation of plant-pesticides that may present novel exposures.

The Agency also included a question, at the January 21, 1994, joint BSAC/SAP meeting, concerning an approach using a criterion based on the process used to modify the plant, e.g., recombinant DNA methodologies. As described in the report of the joint BSAC/SAP Subpanel meeting, if the Agency were to use this approach, it would first exempt plant-pesticides developed through techniques other than those of modern biotechnology from its regulatory scope. For those plant-pesticides that are *not* exempted because they were developed through techniques of modern biotechnology, the exemptions proposed by the Agency would apply (see Units IV.B. and IV.C. of this document).

The joint Subpanel supported the inclusion of a criterion based on methodologies such as rDNA as a rational approach to making the first cut as to which plant-pesticides would be regulated. However, the joint Subpanel cautioned that further exemptions such as those proposed by EPA should be used in conjunction with the criterion based on methodology. In addition, the

joint Subpanel recommended that the Agency define methodologies in a way that clearly delineates to the scientific community and the public what is and is not included in the regulatory scope, based on current state-of-the-science.

EPA Response: The Agency has chosen to propose to use under both statutes, an approach based on sexual compatibility. First, this approach would exempt under both FIFRA and FFDCA, plant-pesticides having a high probability of being derived from plants having high numbers of genes in common. Under such circumstances, the likelihood of new or novel exposures both to the environment and in terms of human consumption is low.

Second, use of the standard of sexual compatibility will allow EPA to use its authorities under FIFRA and FFDCA in concert to regulate plant-pesticides, and thus to utilize, to the extent possible in light of the different statutory standards, similar approaches to oversight under each of the two statutes.

Third, the Agency believes that its proposed approach would be consistent with the SAP Subpanel's concern that EPA ". . .create a workable balance between effective regulatory oversight and encouragement of the development of plant-produced pesticides." Under the preferred approach, novel exposures are not likely to occur with plant-pesticides exchanged between plants that are sexually compatible (See also Unit V. of this document for additional discussion).

With regard to the advice of the January 21, 1994, joint SAP/BSAC Subpanel concerning the use of a process-based criterion in the scope, if the Agency were to use this approach, plant-pesticides developed through techniques other than those involving *in vitro* manipulation of genetic material would be exempt. In order to meet the recommendations of the joint Subpanel, the Agency would define this category of plant-pesticides in the following way: The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is extracted from an organism and introduced into the genome of the recipient plant or is synthesized *in vitro* and introduced into the genome of the recipient plant. The exemptions proposed by the Agency in Unit IV. of this document would be used in concert with this criterion. The Agency believes this approach would meet the recommendations of the SAP/BSAC joint Subpanel. The Agency is soliciting comment on this approach (see the proposal published elsewhere in today's issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule").

B. Plant-pesticides That Act Primarily by Affecting the Plant

The SAP Subpanel at its December 1992 meeting considered whether EPA's language clearly and sufficiently identified plant resistance mechanisms that do not involve substances whose mode of action produces a direct toxic effect on the pest. The SAP Subpanel stated that for the most part the language EPA was proposing was clear and appropriately identified plant resistance mechanisms whose mode of action was not directly toxic. The Subpanel noted, however, that the issue of resistance to toxins produced by the pests was not addressed by that language. The Subpanel recommended insertion of the following statement into EPA's proposed language: "Acts in the host plant to produce target(s) of the toxin that are resistant to the toxin's deleterious action."

EPA Response: EPA accepted this recommendation and modified the language of its approach to incorporate the issue of resistance to toxins.

C. Viral Coat Proteins

1. *FIFRA*. The December 18, 1992, SAP Subpanel meeting and the January 21, 1994, joint SAP/BSAC Subpanel meeting addressed the use of viral coat protein genes to modify plants to protect the plant from damage from viral infection. In the discussion at the December 18, 1992, SAP Subpanel meeting, several risk considerations were identified and the probability of occurrence of each addressed in the SAP Subpanel report. The SAP Subpanel report stated that the probability of occurrence of the risks examined is very low (see Unit IV.B.1.c.iii. of this document and the proposal published elsewhere in todays issue of the **Federal Register** entitled, "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule," for a more complete discussion). The January 21, 1994, joint SAP/BSAC Subpanel meeting discussed the alternative option for the exemption of viral coat proteins from FIFRA regulation. The joint Subpanel reiterated the statement of the December 18, 1992, SAP Subpanel report that the potential risks associated with the use of vcp-mediated resistance coat proteins are low. The SAP/BSAC joint Subpanel, at the January 21, 1994 meeting, did not support the inclusion of the alternative partial exemption option. Unit IV.B.1.c. of this document describes how the SAP and joint SAP/BSAC discussion of vcp-mediated resistance viral coat proteins supplements and influences EPA's analysis.

EPA Response: EPA agrees that the probability of risks from the introduction of viral coat protein genes into plant genomes is low, and as its preferred option proposes to exempt these plant-pesticides from FIFRA oversight. Because of public comments received at the December 18, 1992, SAP Subpanel meeting and the January 21, 1994, joint SAP/BSAC meeting, however, concerning viral coat proteins and selective advantage to wild relatives of managed plants, EPA is offering for comment in this document the alternative approach to viral coat proteins to allow the fullest discussion possible.

2. *FFDCA*. The December 18, 1992, SAP Subpanel also addressed the question of whether viral coat proteins might present a dietary risk. It stated that "[s]ince viruses are ubiquitous in the agricultural environment at levels higher than will be present in transgenic plants, and there has been a long history of 'contamination' of the food supply by virus coat protein, there is scientific rational for exempting transgenic plants expressing virus coat protein from the require of a tolerance."

EPA Response: EPA agrees with this position and is proposing an exemption from the requirement of a tolerance for viral coat proteins.

D. Nucleic Acids

The BSAC Subcommittee on July 13, 1993, confirmed that nucleic acids (DNA and RNA), are present in the cells of every living organism, including plants, microorganisms and animals, used for food, and do not raise safety concerns as a component of food.

EPA Response: EPA agrees with the BSAC Subcommittee and is proposing to exempt nucleic acids (DNA and RNA) as a class from the requirement of a tolerance under FFDCA.

E. Pest Resistance

The SAP Subpanel on December 18, 1992, addressed the issue of development of pest resistance to a pesticidal substance produced by plants. The Subpanel stated that "[d]elaying the evolution of resistance is clearly important if we are to realize the full potential of effective and safe crop protection that could be obtained by application of biotechnology." The SAP Subpanel urged EPA to actively assess the problem of pesticide resistance, especially when the pesticide is part of the progression toward use of "safer pesticides."

EPA Response: EPA agrees that the issue of the development of resistance is an important one and is examining what it might do to address this issue under its regulatory authorities.

F. Allergenicity

The December 18, 1992, SAP Subpanel, in its discussion of EPA's approach for oversight of plant-pesticides under FFDCA, raised the question of the potential allergenicity of certain food components.

EPA Response: EPA is aware that there are food components that can induce food allergies and that the issue of allergenicity in novel foods is important. EPA hosted, along with FDA and USDA/APHIS, a scientific conference on food allergens on April 18–19, 1994. The agencies are now reviewing the discussions that were held at the conference.

G. In Vitro Digestibility Assay

EPA asked the July 13, 1993, BSAC Subcommittee to consider the scientific merits and limitations of an *in vitro* digestibility assay to predict toxicity from dietary exposure to proteinaceous transgenic plant pesticides. This *in vitro* digestibility assay would use features of the test, 701- Disintegration for Plain Coated Tablets or Enteric-coated Tablets, of the US Pharmacopeia.

The Subcommittee responded to the following specific questions on the *in vitro* digestibility assay. What are the appropriate assay endpoints (i.e., free amino acids, peptides) to conclude that a protein is digested to harmless components? What are the best methods to quantify digestibility? With plant associated proteinaceous pesticides, what is the most relevant test material? How predictive is the *in vitro* assay for addressing the variations in luminal adsorption that occur with maturation, (i.e., infant versus adult versus geriatric uptake)? What is the significance of digestive disorders like hypochlorhydria and enzyme deficiencies with respect to the *in vitro* digestibility assay and interpretation of assay results? To what extent can the amino acid sequence of known toxic proteins and known sequences of non-toxic proteins be used to predict toxicity or lack of toxicity in other proteins? Would fragments of non-toxic proteins also be expected to be non-toxic?

In response, the Subcommittee indicated that it could not endorse use of an *in vitro* digestibility assay as the sole test for determining toxicity. An *in vitro* digestibility assay might provide useful information if employed in conjunction with other tests.

The Subcommittee suggested that if an *in vitro* digestibility test assay is to be used as part of a more comprehensive toxicological evaluation, the test should utilize a range of gastric and intestinal phases in order to address variations in luminal absorption that occur with maturation.

In response to the question concerning the appropriate test material, the Subcommittee suggested the test be conducted with purified plant-pesticide. Purified plant-pesticide may be tested in the presence or absence of standardized mixtures, (e.g., protein/agar). The standardized mixture would approximate the condition of a plant-pesticide ingested in food.

With regard to the question concerning how to best quantify digestibility, the Subcommittee suggested a Western blot could be used to determine the degree of digestion of the plant-pesticide.

In response to the question on what constitutes the appropriate test material and assay endpoint and the question of whether fragments of non-toxic proteins could be expected to be non-toxic, the Subcommittee noted that partially digested proteins and peptides may be toxic even if the parent protein is not. They suggested it may therefore be difficult to declare anything short of complete digestion to amino acids as non-toxic.

The Subcommittee suggested the Agency consider exploring other methods of addressing the issue of toxicity from dietary exposure, including: *in vitro* cell and culture systems to address questions of digestibility, translocation/transport across the lumen, and binding to cells of the GI tract; feeding studies involving whole animal systems, specifically those involving "failure to thrive" assays; cell binding assays to test for the presence of receptors for toxins; an *in vivo* assay using brine shrimp. The Subcommittee cautioned, however, that the brine shrimp or other nonmammalian test systems need to be evaluated carefully to ensure that the data can be extrapolated to mammalian species and to determine that the test responds appropriately to proteinaceous plant-pesticides. The Subcommittee indicated that EPA may have to rely on a case-by-case approach to assessing toxicity for the near future.

EPA Response: EPA is exploring the suggestions of the BSAC Subcommittee as it develops its data requirements for plant pesticides.

H. Points to Consider for Data Needs

EPA asked the January 21, 1994, joint SAP/BSAC Subpanel to consider the "points to consider" EPA had developed for plant-pesticides in terms of product analysis, ecological effects, environmental fate, and human health effects.

1. *Product analysis.* In terms of product analysis, the joint Subpanel endorsed the Agency position that the evaluation of the risks posed by plant-pesticides demands that methods be available for product analysis and characterization of plant-pesticides in terms of: (1) Identification of the donor organisms and gene sequences that are inserted into the recipient plant; (2) identification and description of the vector or gene delivery systems; (3) identification of the recipient organisms, including information on the insertion of the gene sequences; (4) chemical characterization of the plant-pesticide products; and (5) quantification of the plant-pesticides in recipient plants.

The joint Subpanel suggested some additional information may be useful: (1) Are the gene sequences stable in the recipient organism or are they prone to deletion or mutation?; (2) The chemical characterization of the plant-pesticides should be equally rigorous whether the products are proteinaceous or nonproteinaceous; (3) Methods for quantification of plant-pesticides are essential for assessing exposure to target and nontarget organisms, for assessing human exposure, for determining environmental fate, transport, and persistence, and for determining the distribution (i.e., in edible and nonedible portions) of plant-pesticides within plants.

2. *Ecological effects.* In terms of ecological effects, the joint Subpanel stated that EPA in its proposed policy statement addresses the major issues of concern in assessing the ecological risks associated with the testing and commercialization of plant-pesticide products. They suggested, however, that there are several points that could be expanded to better address potential ecological risks. These are:

(1) Substances to be tested: While a case-by-case determination is appropriate, it is important that the substance be tested in an ecologically relevant form under an ecologically relevant protocol. Unlike conventional pesticides for which direct contact with the pesticide is a primary means of exposure, exposure to plant-pesticides will be primarily through ingestion of, or contact with, pesticide-containing plant tissues. Experience with bioassays of plant defensive chemicals has shown the plant milieu, and the method of exposure, may dramatically modify (enhance or ameliorate) the resultant

effects of the chemical. Consequently, test substances and test protocols that lack ecological relevance may provide results that are inappropriate as a basis for regulatory decisions. The joint Subpanel recommended that EPA develop a series of guidelines for identifying ecologically relevant test substances and develop ecologically relevant test protocols.

(2) The joint Subpanel noted that EPA identifies expression of the plant-pesticide by the plant throughout the entire plant life-cycle as a consideration in determining the potential for chronic exposure on nontarget species to the plant-pesticide. Because plant life-cycles can vary in duration, and because exposure of nontarget species to a plant-pesticide for periods of shorter duration than a plant's life-cycle could have potentially significant ecological effects, expression of the pesticidal substance throughout the plant's life cycle seems to be a criterion that is not necessarily relevant in an ecological context. Although recognizing that it would lack the regulatory consistency of the plant life-cycle criterion, the joint Subpanel concluded that a criterion based on expression of the plant- pesticide for "prolonged periods" would seem to have greater ecological relevance. The joint Subpanel also stated that the meaning of "prolonged period" would have to be determined on a case-by-case basis and would depend on the types of nontarget organisms that are likely to be affected. The joint Subpanel recommended that EPA develop guidelines that define the potential for chronic exposure in terms of the duration of expression of the pesticide substance by a plant, relative to the life cycles of nontarget organisms likely to be exposed.

(3) The joint Subpanel also commented on triggers for requiring EUPs for plant-pesticides during the testing stage, noting that the potential for nontarget exposure through gene capture by wild relatives will increase as the number of test sites increases, in areas where wild relatives may occur. Accordingly, the joint Subpanel recommended that EPA give careful consideration to addressing this potential for increased ecological risk in those situations in which there is potential for gene capture by wild plants when establishing an EUP trigger.

3. *Human health effects.* In terms of human health effects, the joint Subpanel noted that nontarget populations at potential risk from exposure to plant-pesticides may include humans and data requirements should take into account the diverse nontarget subpopulations that could be potentially exposed or at risk. Examples of specific subpopulations at potential risk may include individuals who are high consumers (e.g., vegetarians; children with high intake to body weight ratios; over eaters), individuals with compromised digestive systems (e.g., elderly individuals; persons receiving treatment for digestive disorders or diseases).

4. *EPA response.* EPA agrees with the joint Subpanel's suggestions and has considered them in the points to consider and will consider them as the Agency develops its data requirements for plant-pesticides.

IX. Request for Comment

A. Scope of Coverage for the Regulatory Scheme for Plant-Pesticides under FIFRA and FFDCA

1. *FIFRA exemptions*: Requests for comment on the proposed exemptions under FIFRA and the options for these exemptions can be found in the **Federal Register** document entitled: "Plant-pesticide Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule." All comments relating to the proposed exemptions under FIFRA should be submitted in the context of this proposed regulation and should be identified by the docket control number OPP–300369.

2. *FFDCA exemptions*: Requests for comment on EPA's proposed exemption from the requirement of a tolerance for categories of plant-pesticides that will not result in significantly different dietary exposure can be found in the **Federal Register** document entitled, "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act" and should be identified by the docket control number OPP–300368. All comments relating to this proposed exemption from the requirement of a tolerance should be submitted in the context of that proposed regulation. Similarly, all comments relating to the other two proposed exemptions from the requirement of a tolerance should be submitted in the context of these proposed regulations and should be submitted under the docket control numbers OPP–300367 and OPP–300371 (see the proposals published elsewhere in todays issue of the **Federal Register** entitled "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance for Viral Coat Proteins in Plants" and "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance For Nucleic Acids Produced in Plants."

B. EUP Triggers for Field Testing

EPA has described in this **Federal Register** document one preferred approach and four alternative approaches for identifying when producers would be required to obtain an EUP. Commenters are advised that the Agency may choose to implement any of these five approaches or some combination thereof. EPA recognizes that each of these five approaches has advantages and disadvantages. EPA is soliciting comment on these approaches. Commenters in stating a preference for an approach are asked to describe the factors weighing most heavily in forming their preference.

X. Economic Analysis

The regulatory impact analysis (RIA) evaluates the costs and benefits of amending the Code of Federal Regulations to allow for the regulation or exemption of specific types of plant-pesticides under FIFRA (40 CFR 152.20 and 40 CFR part 174). This report is intended to meet the requirements for a RIA as established by Executive Order No. 12866, the Regulatory Flexibility Act, and section 25 of FIFRA.

The RIA presents the alternative regulatory options and the costs that were considered by the Agency under FIFRA, including two options that were considered by the Agency but not included in the proposed rule. Four possible approaches to the regulation of plant-pesticides under FIFRA were evaluated in the RIA that allowed for varying degrees of regulatory coverage. RIA Option 1 is the most limited alternative in regulatory scope. RIA Option 2 represents EPA's proposed, and preferred, regulatory scope and is broader in coverage than RIA Option 1. In addition to those plant-pesticides regulated under RIA Option 2, RIA Option 3's scope would include viral coat proteins used as plant-pesticides. Finally, under RIA Option 4, all plant-pesticides, including those that result from traditional plant breeding, would be subject to the requirements of FIFRA. The costs for RIA Option 2 (the Agency's preferred option) are substantially lower than RIA Option 4. Refer to the proposal published elsewhere in todays issue of the **Federal Register** entitled "Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule" for a summary of the RIA. The entire text of the RIA can be found in the public docket for this proposed rule (OPP–300370).

XI References

(1) EPA issue paper. FIFRA: Benefit and environmental risk considerations for inherent plant-pesticides.

(2) EPA issue paper. Issues associated with the regulation of viral coat proteins under FIFRA and FFDCA.

(3) Food and Drug Administration. 1992. Foods derived from new plant varieties. (57 FR 22984).

(4) Klaasen, C.D., M.O. Amdur, and J.D. Doull. 1986. Casarett and Doull's Toxicology: The Basic Science of Poisons. Third Edition. Macmillan Publishing Company, New York.

(5) International Food Biotechnology Council, 1990. Biotechnologies and food: Assuring the safety of foods produced by genetic modification. In: Regulatory Toxicology and Pharmacology. Vol. 12. Academic Press, New York.

(6) Lamb, C.J., J.A. Ryals, E.R. Ward, and R.A. Dixon. 1992. Emerging strategies for enhancing crop resistance to microbial pathogens. Bio/Technology. 10:1436–1445.

(7) Tabashnick, B.E., M.L. Cushing, N. Finson and M.W. Johnson. 1990. Field development of resistance to *Bacillus thuringiensis* in diamondback moth (Lepidoptera: Plutellidae). Journal of Economic Entomology. 83:1671-1676.

(8) Tolin, S.A. 1991. Persistence, establishment, and mitigation of phytopathogenic viruses. In: Risk Assessment in Genetic Engineering. Edited by M.A. Levin and H.S. Strauss. McGraw-Hill, Inc., New York. pp 114–139.

XII. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. Pursuant to the terms of this Executive Order, it has been determined that this proposed policy statement is a "significant regulatory action" because it raises novel policy issues arising out of FIFRA legal mandates. As such, this action has been submitted to OMB for review, and any comments or changes made in response to OMB suggestions or recommendations, will be documented in the public record.

B. Regulatory Flexibility Act

This proposed policy statement was reviewed under the provisions of section 3(a) Regulatory Flexibility Act (RFA) [5 U.S.C. 605(b)]. The RFA requires that agencies take special note of the impact of proposed regulations on small entities. Analysis requirements under the RFA can and should be combined with the analysis required under Executive Order 12866.

The regulatory flexibility analysis of this proposed policy for plant-pesticides on small entities is demonstrated within the structuring of the four regulatory options proposed. These options were considered after extensive evaluations of the benefit/risk tradeoffs between option cost and risk reduction provided. The Agency has structured the resulting options from a narrow regulatory scope (RIA Option 1) to a broad regulatory scope (RIA Option 4) and as such, has conducted an "inherent" sensitivity analysis for small firms likely to be affected by this regulation. The Agency has determined that the tradeoffs between the benefits and risks of the proposed regulations are optimized under RIA Option 2, EPA's proposed scope.

C. Paperwork Reduction Act

The information collection requirements in this proposed policy statement have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq* An Information Collection Request document has been prepared by EPA (ICR No. 1693.01) and a copy may be obtained from Sandy Farmer, Information Policy Branch, (Mail Code 2136), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, or by calling (202) 260–2740.

This collection of information has an estimated reporting burden averaging 1,143 hours per response and an estimated annual recordkeeping burden averaging 74 hours per respondent. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch, (Mail Code 2136), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposed policy statement.

List of Subjects

Environmental protection, Biotechnology, Labeling, Plant-pesticides, Plants.

Dated: November 15, 1994.

Carol M. Browner,

Administrator.

[FR Doc. 94–28821 Filed 11–22–94; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 152 and 174

[OPP-300369; FRL-4755-3]

RIN 2070-AC02

Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The substances plants produce to protect themselves against pests and disease are considered to be pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) definition of "pesticide" (i.e., if they are "... intended for preventing, destroying, repelling or mitigating any pest. . ."). These substances, along with the genetic material necessary to produce them, are designated "plant-pesticides" by EPA. EPA proposes to amend an existing regulation and to create a new regulation to clarify the relationship between plants and plant-pesticides and their regulatory status under FIFRA. EPA also proposes to exempt from FIFRA requirements classes of plant-pesticides that the Agency has determined pose low probability of risk and are not likely to cause unreasonable adverse affects on the environment. Recognizing the unique characteristics of plant-pesticides, the Agency proposes to create a new part in the CFR for regulations unique to plant-pesticides.

DATES: Comments identified by the docket control number [OPP-300369] must be received on or before January 23, 1995.

ADDRESSES: Submit written comments by mail to: Program Resources Section, Public Response and Program Resources Branch, Field Operations Division (7506C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the Virginia address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Bernice Slutsky, Science and Policy Staff, Office of Prevention, Pesticides and Toxic Substances (7101), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone number: (202) 260-6900.

SUPPLEMENTARY INFORMATION:

I. Introduction

EPA proposes to clarify the regulatory status, under FIFRA, of pesticidal substances produced in plants (plant-pesticides) and of plants that produce pesticidal substances and act as biological control agents. EPA defines a biological control agent as "any living organism applied to or introduced into the environment that is intended to function as a pesticide against another organism declared to be a pest by the Administrator" (40 CFR 152.3). EPA also proposes to exempt from FIFRA regulation certain types of pesticidal substances produced in plants that EPA believes do not warrant regulation.

In the **Federal Register** of June 2, 1982 (47 FR 23928), EPA promulgated a final regulation under FIFRA section 25(b) that exempted all biological control agents, except for certain microorganisms, from the requirements of FIFRA. This exemption was promulgated because EPA found that the risks posed by biological control agents other than microorganisms were adequately addressed by other Federal agencies such as the U.S. Department of Agriculture's (USDA's) Animal and Plant Health and Inspection Service (APHIS) and the U.S. Department of the Interior. Although plants used as biological control agents were not specifically addressed in 40 CFR 152.20 or in the June 2, 1982, **Federal Register** document, EPA has considered these plants to be excluded from regulation under FIFRA through this exemption. EPA continues to believe that plants used as biological control agents are adequately regulated by other Federal agencies. However, EPA believes that the status of pesticidal substances produced in plants (i.e., plant-pesticides) requires regulatory clarification.

Although plants used as biological control agents were exempted from FIFRA regulation under 40 CFR 152.20, substances that are extracted from plants and used as pesticides are not similarly exempted. For example, chrysanthemums produce pyrethrum, a substance that has insecticidal activity. Chrysanthemums that produce pyrethrum are exempt from regulation when used as biological control agents (i.e., living chrysanthemums), but pyrethrum itself, as the pesticide substance, is not exempt when it is extracted from chrysanthemum plants and applied to other plants as an insecticide.

This distinction is reasonable in light of the potential for increased and unique exposures due to large-scale application of extracted pyrethrum to plants that do not naturally produce it. The use of extracted pyrethrum as an insecticide can involve exposure to the pesticide over large acreages, whereas the exposure associated with pyrethrum produced by living chrysanthemum plants would not be expected to reach such proportions. In addition, application of pyrethrum beyond the environment in which it is normally produced (i.e., beyond the living chrysanthemum plant) could result in new or unique exposures of nontarget organisms, including humans.

Although it has been EPA's policy under FIFRA to regulate pesticidal substances that have been extracted from plants, to date the Agency has not clearly stated its policies for regulation of pesticidal substances that are produced in living plants and function *in situ* to protect the plant from pests or disease (i.e., not extracted from the plants). This proposed rule is designed to provide such clarification.

FIFRA section 2(u) defines "pesticide" as: "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant. . . ." The substances that are produced in plants to protect them against pests and disease are considered to be pesticides under the definition of FIFRA section 2, (i.e., if they are ". . . intended for preventing, destroying, repelling, or mitigating any pest. . .") regardless of whether the pesticidal capabilities evolved in the plants or were introduced by traditional breeding or through the techniques of modern biotechnology. These substances, along with the genetic material necessary to produce them, are designated "plant-pesticides" by the Agency.

There are a number of types of substances produced in plants that enable plants to resist pest attack and disease. These substances include both those pesticidal substances that would be considered normally a component of

a plant and those that would be considered new to a plant. Examples of plant-pesticides that would be considered normally a component of a plant are phytoalexins (plant-produced substances that act against phytopathogenic microorganisms). An example of a plant-pesticide that would not be considered normally a component of a plant is the insecticidal delta endotoxin that is produced in the bacterium, *Bacillus thuringiensis*.

This proposal would clarify the relationship between plants and plant-pesticides. It applies to all pesticidal substances produced in living plants, including bryophytes such as mosses, seedless vascular plants such as ferns, gymnosperms such as conifers, and angiosperms such as most major crop plants. This proposal would reaffirm that plants continue to be exempt under 40 CFR 152.20 and, under a new part 174 (in the 40 CFR) would codify which categories of plant-pesticides would be exempt and which would be regulated by EPA under FIFRA. Recognizing the unique characteristics of plant-pesticides, the Agency will, in the future, include, in part 174, other regulations specific to plant-pesticides.

As part of the effort to develop this proposal, EPA requested advice from two scientific advisory committees at three meetings. On December 18, 1992, a Subpanel of the FIFRA Scientific Advisory Panel (SAP) was convened to review a draft proposed policy statement and to answer a series of scientific questions concerned primarily with EPA's proposed approach for plant-pesticides under FIFRA. On July 13, 1993, a Subcommittee of the EPA Biotechnology Science Advisory Committee (BSAC) was convened to address a series of scientific questions concerned primarily with EPA's proposed approach for plant-pesticides under the Federal Food, Drug, and Cosmetic Act (FFDCA). On January 21, 1994, a joint BSAC/SAP Subpanel was convened to address a series of scientific questions concerned with the scope of regulation under both FIFRA and FFDCA and guidance for data needs for the evaluation of plant-pesticides.

This proposed rule is one of several documents published in today's issue of the **Federal Register** that address EPA's approach to regulating plant-pesticides. The other documents are: (1) A proposed policy statement that generally describes how EPA proposes to regulate plant-pesticides under FIFRA and the FFDCA ("Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act; Proposed Policy"; (2) a proposed exemption from the requirement of a tolerance for categories of plant-pesticides that do not result in significantly different dietary exposures ("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act"; (3) a proposed exemption from the requirement of a tolerance for coat proteins from plant viruses ("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants" and (4) a proposed exemption from the requirement of a tolerance for nucleic acids produced in plants as part of a plant-pesticide ("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants").

II. Statutory Authority

This rule is being proposed under the authority of section 3 and section 25(a) and (b) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et. seq.*). FIFRA section 2(u) defines "pesticide" as: "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant . . . "

FIFRA section 3 provides that no person may distribute or sell in the United States any pesticide that is not registered under the Act. Before a product may be registered as a pesticide under FIFRA, it must be shown that when used in accordance with widespread and commonly recognized practice, it will not generally cause "unreasonable adverse effects on the environment." FIFRA section 2(bb) defines the term "unreasonable adverse effects on the environment" as any unreasonable risk to humans or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. Thus, FIFRA involves a balancing of the risks presented by the use of the pesticide against the benefits associated with the use of that pesticide.

In addition, FIFRA section 3(a) provides that, to the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale or use of any pesticide that is not registered under FIFRA or subject to an Experimental Use Permit under FIFRA section 5 or subject to an emergency exemption under FIFRA section 18.

Under FIFRA section 25(b), EPA may exempt, by regulation, any pesticide determined to be adequately regulated by another Federal agency, or of a character which is unnecessary to be subject to the Act in order to carry out the purposes of the Act.

III. 40 CFR Part 174

EPA is proposing to set forth, under FIFRA, a new part in 40 CFR specifically for plant-pesticides regulated under FIFRA. In proposed part 174, as well as at § 152.20, EPA would clarify the regulatory relationship between plants and plant-pesticides and, at § 174.5, EPA would define the scope of regulation for plant-pesticides under FIFRA. Although EPA is not proposing in today's issue of the **Federal Register** specific regulatory requirements for plant-pesticides in part 174 (e.g., labeling and Experimental Use Permit requirements), EPA plans to propose such regulations in the future. In the interim period before these additional regulatory amendments are proposed and promulgated, EPA will use existing pesticide regulations (see 40 CFR parts 152 to 173 and 40 CFR parts 177 to 186) for plant-pesticides where applicable. However, these existing regulations were developed generally for traditional, chemical pesticides. Because of the unique characteristics of plant-pesticides, EPA recognizes that the existing regulations may not always be appropriate for these products. The characteristics of plant-pesticides such as both their production and use *in* plants; their biological properties; and their potential ability to spread and increase in quantity in the environment distinguishes them from traditional, chemical pesticides. The Agency therefore intends to apply the existing regulations to plant-pesticides in a manner that addresses the unique issues associated with plants. Producers are encouraged to consult with the Agency well in advance of any proposed activities involving plant-pesticides. (Refer to the **Federal Register** document entitled, "Proposed Policy; Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act.")

IV. Definitions

Because of the unique nature of plant-pesticides, the Agency is proposing certain definitions that will apply to plant-pesticides only. These definitions are contained in the proposed regulatory text under 40 CFR 152.3, and in 40 CFR 174.3. The following unit describes the key definitions for plant-pesticides

under FIFRA and the rationales underlying these definitions.

A. Definition of Plant-pesticide

EPA would define "plant-pesticide" under FIFRA as:

A pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

EPA is including the genetic material necessary to produce the substance in the proposed definition of plant-pesticide for a number of reasons. First, it is the genetic material that is introduced into the plant with the intent that it will ultimately result in a pesticidal effect. Additionally, EPA's regulation of pesticides is based on an evaluation of the potential for unreasonable adverse effects associated with the pesticidal substance, in this case, the pesticidal substance produced in the plant. Regulation also includes risk management considerations. A focus on the genetic material would permit the Agency to address the potential for the spread of the pesticidal substance in the environment through the spread of the genetic material necessary for the production of the substance. Moreover, the amount of pesticidal substance likely to be produced by the plant is also an important consideration that the Agency may, in some circumstances, be able to address through the inclusion of genetic material in the definition of plant-pesticide. In addition, including the genetic material in the definition of plant-pesticide would permit the Agency to address plant-pesticides during stages of the plant's life cycle or in plant parts where the pesticidal substance itself is not produced or is produced in very small amounts (e.g., in pollen or seed). In these cases it is technically easier to verify the presence of the genetic material than the pesticidal substance.

B. Definition of Active and Inert Ingredients

The regulation of pesticides under FIFRA entails the identification of "active ingredients" and "inert ingredients." Under FIFRA section 2, the term active ingredient means ". . . an ingredient which will prevent, destroy, repel, or mitigate any pest. . . [or acts as a plant regulator, defoliant or desiccant]." The term inert ingredient means ". . . an ingredient which is not active." EPA recognizes that plant-pesticides have certain characteristics that are different from those of more traditional chemical pesticides. EPA believes that the overall characteristics of plant-pesticides require specifically tailored active and inert ingredient definitions.

In light of this consideration, EPA proposes to use the following definitions for plant-pesticides.

Active ingredient, when referring to plant-pesticides only, means a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

Inert ingredient, when referring to plant-pesticides only, means any substance, such as a selectable marker, other than the active ingredient, and the genetic material necessary for the production of the substance, that is intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient.

Note that the plant-pesticide active ingredient is the plant-pesticide and therefore the proposed definition of active ingredient for plant-pesticides is the same as the definition of plant-pesticide. The plant-pesticide product includes both the active and inert ingredients.

The definition of plant-pesticide and the active and inert ingredient definitions would include all of the genetic material "necessary for the production" of the pesticidal and inert substance. The following genetic regions are considered "necessary for the production" of the plant-pesticide active and inert substances: (1) The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance, and (2) regulatory regions such as promoters, enhancers, and terminators.

The genetic material can either directly encode for the pesticidal substance or may encode for enzymes that lead to the production of a pesticidal substance (e.g., phenylalanine ammonia-lyase (PAL) catalyzes the first reaction in the synthesis of such phytoalexins as pterocarpans in *Leguminosae* and furanocoumarins in *Solanaceae* and *Umbelliferae*; Ref. 4). It might also include genetic regions encoding for RNA that acts as the pesticidal substance or leads to the production of the pesticidal substance (e.g., antisense mRNA). The active and inert ingredients would also include any regulatory regions, such as promoters, that control the expression of the genetic material encoding for the pesticidal or inert substance or leading to the production of the pesticidal or inert substance and are introduced into the plant along with that gene. For example, a different regulatory element could lead to the production of the pesticidal substance in new plant parts or for new durations, resulting in new exposure scenarios.

The genetic material "necessary for the production" of the plant-pesticide active and inert substances does not include genetic regions that are not involved in DNA expression (i.e., noncoding, nonexpressed sequences such as linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites). However, the Agency would require information concerning these sequences if it determines that such information is necessary for the evaluation of the active or inert ingredient.

There may be genetic material encoding other functions (e.g., genetic material intended to alter the amount of carbohydrate in the plant) that are introduced into the plant along with the active and inert ingredients. These activities would be subject to the Food and Drug Administration (FDA) authorities.

V. Proposed Exemptions for Plant-pesticides

EPA has attempted to identify those types of plant-pesticides that have greater potential for environmental and/or human health risks and to focus its regulatory scrutiny on these plant-pesticides. To exempt from regulation those plant-pesticides having low potential for risk, EPA is proposing to employ its exemption authority under FIFRA section 25(b). FIFRA section 25(b)(2) allows the Agency to exempt a pesticide from the requirements of FIFRA if it is of a character unnecessary to be subject to the Act in order to carry out the purposes of the Act. Through FIFRA section 25(b)(2), EPA proposes to exempt certain categories of plant-pesticides that EPA believes pose low probability of risk and are not likely to cause unreasonable adverse effects even in the absence of any regulatory oversight under FIFRA and, thus, are of a character unnecessary to be subject to the Act. Those plant-pesticides not exempted would form the scope of EPA's regulatory scrutiny under FIFRA.

EPA finds that the plant-pesticides it is proposing to exempt have a low probability of risk and have potential benefits associated with them (e.g., economic benefits to farmers and reducing the need for chemical pesticides) that outweigh any potential risks associated with them, and that the low probability of risk does not justify the cost of regulation. Therefore, the Agency proposes under 40 CFR 174.5 to exempt, from FIFRA regulation, the categories of plant-pesticides that EPA has identified as those that are likely to

pose little risk and are not likely to cause unreasonable adverse effects on the environment even in the absence of regulatory oversight.

While EPA's analysis of the potential risks and benefits of plant-pesticides has led the Agency to the conclusion that some categories of plant-pesticides warrant regulation while others do not, the Agency cannot foresee all potential adverse effects to human health or the environment which may potentially arise for testing and use of specific plant-pesticides. Thus, in § 174.7 EPA is proposing to require reporting of information on adverse effects from the testing and use of plant-pesticides that EPA is proposing to exempt in § 174.5. Proposed § 174.7 is meant to address unforeseeable events resulting from use of such pesticides. EPA believes that such events are likely to be extremely rare; however, § 174.7 is a means of ensuring that any potential risk is addressed and that the Agency's data base is as complete as possible. Information on potential unreasonable adverse effects would be required to be reported if such information is obtained, from any source, by any person who sells or distributes a plant-pesticide. Failure to comply with § 174.7 would be an unlawful act under FIFRA section 12(a)(2)(S) and could result in an enforcement action (for penalties) under FIFRA section 14. In addition, FIFRA section 6(a)(2) applies to plant-pesticides that would not be exempt under this proposed rule.

As with traditional pesticides, the underlying considerations in analyzing risks posed by plant-pesticides are the potential for exposure to the pesticidal substance and hazards of the pesticidal substance to humans, other nontarget organisms, and the environment. For plant-pesticides, exposure and hazard will be determined by the chemical and toxicological properties of the pesticidal substance and the biological characteristics of the plant that is producing the substance.

The properties of the plant-pesticide, including the mechanism by which it affects the target pest, will determine the potential for hazards to nontarget organisms, including humans. The type of organism exposed to the plant-pesticide will be determined by the characteristic of the plants that produce the substance and the environment where the plants are grown; e.g., whether the production of the substance is limited to particular plant parts, the organisms that normally associate with the plant, and the acreage and location planted. An important consideration not seen with traditional pesticides is the potential for spread of the plant's genetic material. Because plants can reproduce sexually and/or asexually, the ability to produce the plant-pesticide could spread through the agro- or natural ecosystems, particularly if wild relatives acquire the ability to produce the plant-pesticide through successful hybridization.

Such hazard and exposure considerations form the bases of the three exemptions, discussed in Units V.A., V.B., and V.C. of this preamble, that the Agency is proposing for plant-pesticides under FIFRA.

The benefits associated with use of some categories of plant-pesticides include the economic benefit to farmers for use of plant-pesticides in circumstances where traditional pesticides may not be as effective (e.g., for some systemic plant pests) or may be more expensive, thus increasing crop yield and/or reducing farmers' costs. An additional benefit is the environmental benefit associated with potential reduced use of pesticides that may be less environmentally benign than these plant-pesticides.

A. Exemption of Plant-pesticides Derived from Closely Related Plants

A primary consideration in evaluating plant-pesticides is the potential for new exposures of nontarget organisms to the pesticide. If a plant normally produces a pesticidal substance, organisms that come in contact with the plant have likely been exposed to that substance in the past, perhaps over long periods of time. The potential for new exposures to occur would be very low.

In contrast, if a plant-pesticide is not normally produced by a plant, the organisms that come in contact with the plant may never have been exposed to the substance. For instance, certain spiders produce a toxin that is targeted for their insect prey. Plants are not known to produce this toxin in nature or in cultivation. If this toxin were to enter the gene pool of specific plants, organisms that had never previously been exposed to the toxin could now be exposed. Prior to the introduction of the toxin into these plants, only the insect prey of the spider would potentially be exposed to the toxin. If plants could now express the toxin, a different or larger group of organisms could be exposed to it, possibly resulting in adverse effects to these organisms. For instance, insects that feed on the plant could be exposed to the toxin. If the toxin is found in pollen, pollinators could also be exposed.

EPA is proposing to concentrate its regulatory efforts under FIFRA on those plant-pesticides that are new to the plant and, thus, have the greatest potential for exposing nontarget organisms to a new pesticidal substance. The Agency is proposing to exempt from FIFRA regulation those plant-pesticides that are normally a component of (not new to) a plant. In defining, for regulatory purposes, those substances it considers to be normally a component of a plant, the Agency is presenting three approaches to the proposed exemption for public comment. In selecting among these three options, the Agency will consider how well each of the options: (1) Distinguishes, on a risk basis, those plant-pesticides that would result in new environmental exposures from those that would not; (2) provides a standard of sufficient regulatory clarity so that the public, industry, and the Agency can easily identify those plant-pesticides that would be subject to regulation; (3) does not place an undo burden on producers/developers; and (4) creates as similar a scope of regulation as possible for this exemption under FIFRA as EPA is proposing under FFDCA, given the differences in mandate and structure of the two statutes. The three options are described below followed by a description of terms used in the options in Unit V.A.4. of this preamble and an analysis of the options in Unit V.A.5. of this preamble. For the reasons discussed in Unit V.A.5. of this preamble, EPA prefers Option 1 over Options 2 or 3.

1. *Option 1: Plant-pesticides derived from sexually compatible plants.* This approach is based on the concept of sexual compatibility. The Agency believes this concept describes a measure of relatedness between plants and views plant-pesticides moved between sexually compatible plants as not new to the plant. The use of the standard of sexual compatibility is embodied in the following language from the proposed regulatory text: [Plant-pesticides are exempt from FIFRA requirements if:]

> . . .The genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from plants that are sexually compatible with the recipient plant and has never been derived from a source that is not sexually compatible with the recipient plant; . . .

2. *Option 2: Plant-pesticides derived from plants within the same genus.* A second approach that EPA is considering for defining when a plant-pesticide is new to the plant is a standard based on taxonomy. Under this approach, the standard would rely on the taxonomic grouping of genus; plant-pesticides moved between plants in the same genus would be exempt. The

assumption under this approach is that the genus grouping correlates with a relatively high degree of relatedness among plants even though not all plants in a genus are sexually compatible. Similarity in traits ranging from flower morphology to the presence of particular alkaloids and flavonoids, for example, have been used to determine whether to classify a plant species in a particular genus and these traits likely bespeak a high degree of relatedness. The language defining this option would be as follows: [Plant-pesticides are exempt from FIFRA requirements if:]

The genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from plants that are within the same genus as the recipient plant [regardless of sexual compatibility] and has never been derived from a source outside of that genus;

3. *Option 3: Plant-pesticides derived from plants within the same genus or from sexually compatible plants.* The third approach EPA is considering combines the above two standards of taxonomy and sexual compatibility. The standard under this option would rely primarily on the taxonomic grouping of genus as a measure of relatedness. Recognizing that some plants that are sexually compatible are classified in different genera and assuming that sexual compatibility bespeaks a high degree of relatedness, EPA also includes a provision extending the exemption to include sexually compatible plants from any genera. The language defining this option would be as follows: [Plant-pesticides are exempt from FIFRA requirements if:]

The genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance:

(1) Is derived from plants that are within the same genus as the recipient plant [regardless of sexual compatibility] or, is derived from plants that are sexually compatible with the recipient plant; and

(2) Has never been derived from a source outside the same genus that is not sexually compatible with the recipient plant.

4. *Terms used in the options.* The phrase "genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance" refers to genetic material that: (1) Directly encodes for the pesticidal substance; (2) encodes for enzymes that lead to the production of a pesticidal substance (as in the example of the PAL gene discussed in Unit IV. of this preamble); or (3) encodes for RNA that acts as a pesticide or leads to the production of a pesticidal substance (e.g., antisense RNA).

For the purposes of the options for this exemption under FIFRA, this phrase is not intended to include regulatory regions or noncoding, nonexpressed nucleotide sequences when the genetic material encoding for or leading to the production of the pesticidal substance would otherwise be exempt. For this specific exemption, these regulatory regions and noncoding, nonexpressed nucleotide sequences *may be derived from any source.* For example, if a viral promoter attached to a corn structural gene encoding a pesticidal substance is introduced into another corn variety, the structural gene and the viral promotor genetic construct would meet the criteria of the options for this exemption.

Note that whereas regulatory elements are not, for the purposes of the proposed exemptions, considered part of the genetic material "that encodes for a pesticidal substance or leads to the production" of a pesticidal substance, regulatory elements *are* considered part of the genetic material "necessary for the production" of a pesticidal substance under the definitions of the plant-pesticide active and inert ingredients (see Unit IV. of this preamble).

The definition for "sexually compatible" means being capable of forming a viable zygote through the fusion of two gametes and can include the use of bridging crosses and wide cross breeding techniques such as surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre- and post-pollination hormone treatments, manipulation of chromosome numbers, and embryo culture. It can also include, for the purposes of this exemption, ovary and ovule cultures. EPA believes that the production of viable zygotes through these techniques indicates a sufficient level of relatedness between the parental plants involved to be included under the rubric of "sexually compatible."

The phrase ". . . has never been derived from a source that is not sexually compatible with the recipient plant . . ." is meant to indicate in the proposed regulatory text that the genetic material would not qualify for the exemption if it is introduced into a plant from a sexually incompatible source and subsequently introduced into other sexually compatible plants. An example of such a situation would be if the *Bacillus thuringiensis* delta endotoxin is introduced into wheat and the endotoxin producing wheat subsequently hybridized with rye using wide cross techniques to produce triticale. The endotoxin produced in the triticale would not be eligible for the exemption.

5. *Analysis of options.* EPA's goal in developing these options for defining an exemption under FIFRA is to identify those plant-pesticides with a higher potential for new environmental exposures to nontarget organisms. Under Option 1, the Agency would consider plant-pesticides produced in sexually compatible plants to be least likely to result in these new exposures. Since traits can be passed through a plant population by sexual recombination, it is reasonable to predict that, in a sexually compatible population, new exposures of organisms that associate with plants in the population to the pesticidal substance are unlikely.

Sexually compatible plants are more apt to share traits than are unrelated plants. It is a common expectation that similarity is associated with the degree of relatedness. Natural hybridization and selection have produced groups of plants which have a common gene pool. Generations of artificial hybridization practiced to produce improved crops for cultivation have tended to increase the extent of relatedness among elements of a broader segment of agricultural plants.

The practice of saving seed from desirable plants has been going on for thousands of years and controlled crosses to produce plant hybrids have been documented since the eighteenth century. Since the rediscovery of Mendel's work on the inheritance of traits, there is a base of experience of 50 to 100 years of breeding for most major crops. During that time, it has been common agricultural practice to cross sexually compatible wild relatives with crop plants to develop crop varieties with better pest resistance. Techniques such as genetic mapping reveal the presence of genetic loci in cultivated plants that previously were considered to be present only in the wild species. Sexually compatible crop varieties are also crossed with each other to achieve better pest resistance in their progeny. Because of these common practices, the potential for significantly different environmental exposures from current crop plants is likely to be low.

EPA proposes to extend the concept of sexual compatibility to include wide crosses because wide crosses are commonly used to expand the plant gene pool for varietal improvement, and EPA believes that a fairly high degree of relatedness between the parental plants is indicated when a wide cross produces a viable zygote. However, for regulatory purposes it is somewhat difficult to define what constitutes a wide cross since techniques may change over time.

EPA is thus proposing, for the purposes of this proposed rulemaking, a definition of wide crosses that is based on existing techniques with a provision to add new techniques if they meet the definition.

Options 2 and 3 both rely on taxonomy, and this standard may also represent an acceptable degree of relatedness. Plant species within the same genus may have become separated by geography, timing of pollination, or other factors to form two distinct populations no longer sexually compatible. Events such as mutation and environmental selection can reinforce the isolation and uniqueness of the gene pools. However, the ability to overcome these incompatibility barriers between species in the same genera through human intervention (e.g., bridging crosses and wide crosses) is evidence that such plants are fairly closely related. The majority of successful wide crosses to date have occurred between species within the same genus.

The second option is based solely on the taxonomic standard of genus. Sexual compatibility (including the use of bridging crosses and wide crosses) with the recipient plant would not be a criterion. The third option relies primarily on taxonomy but also includes the standard of sexual compatibility. Unlike Option 2, under this option, plant-pesticides derived from a plant outside of the same genus as the recipient plant could still be eligible for the exemption if sexual compatibility between the source and the recipient plant is demonstrated.

The use of a taxonomic standard may, from a regulatory perspective, be somewhat clearer than a standard based solely on sexual compatibility (including bridging and wide crosses). However, taxonomy may be a more artificial standard than sexual compatibility as a predictor of different environmental exposures of a plant-pesticide, particularly for unmanaged or semi-managed plants. Isolation, adaptation to unique environments, and low natural rates of gene flow even between populations of the same species characterize many natural populations. For these types of plants, the taxonomic standard used in Options 2 and 3 may not be as appropriate as the sexual compatibility standard used in Option 1 with regard to novel exposures to plant-pesticides produced in unmanaged or semi-managed plants. In addition, classification of plants in different genera is not fixed and could change over time and between scientific authorities.

Option 1 is more compatible than either Option 2 or 3 with EPA's preferred approach to plant-pesticides under FFDCA. Under FFDCA, EPA sets tolerances for pesticide residues in foods. EPA may also exempt pesticides from the requirement of a tolerance when such tolerance is not needed to protect the public health. EPA is proposing to exempt from FFDCA requirements certain plant-pesticides that would not result in significantly new dietary exposures as it is proposing to exempt plant-pesticides that would not result in new environmental exposures from FIFRA requirements. Under both statutes, EPA's preferred approach uses the standard of sexual compatibility presented in Option 1 in this document. In addition, using a taxonomic standard alone (Option 2) is not considered a viable option under FFDCA (see **Federal Register** document entitled, "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act."

For some crop plant varieties, e.g., potatoes, vegetative propagation is commonly used in addition to breeding. Since vegetatively propagated plants have the same genetic makeup, EPA intends that a plant-pesticide produced in a vegetatively propagated plant would meet the criteria of Option 1 as long as the plant-pesticide is either produced during vegetative propagation or, during breeding, the original genetic source of the plant-pesticide is sexually compatible with the recipient plant, as defined in the proposed regulatory text. A plant-pesticide produced in vegetative plants would meet the criteria of Option 2 and 3 as long as the plant-pesticide is produced during vegetative propagation or the original genetic source of the plant-pesticide is in the same genus as or, in the case of Option 3, is sexually compatible with the recipient plant.

None of the options presented in this unit are intended to exempt plant-pesticides which are significantly different in structure or function from the plant-pesticide as it occurs in the source plant. Such significantly modified plant-pesticides would not be eligible for exemption under any of the options. Rearrangements or modifications of the sequence encoding a plant-pesticide, for example, could result in plant-pesticides with significantly different structures and/or functions from those in the source plant and these would not be exempt. If this type of modification were to occur, the potential for new and different exposures in the environment could be significant.

Under all of the approaches discussed in this unit, the Agency has evaluated whether changes in the levels of plant-pesticides that plants normally produce would warrant regulation under FIFRA. (Ref. 1) The Agency's analysis indicates that changes in the levels of such plant-pesticides expressed by a plant could result in increased or decreased exposures of nontarget organisms to a plant-pesticide. However, EPA believes, for the reasons outlined below, that the potential for unreasonable adverse effects from these exposures is low and these types of plant-pesticides do not warrant regulation under FIFRA.

In deciding whether and how to regulate such plant-pesticides, EPA first considered whether an increase in the levels of these plant-pesticides is likely to exceed the ranges normally found within and between plant varieties (both cultivated and uncultivated). EPA believes that increases in the levels of such plant-pesticides are not likely to result in overall significantly different exposures of nontarget organisms to the pesticide. The level of production of such pesticidal substances normally varies among related plants because of differences in genetic makeup and environmental conditions. This variation, in turn, results in natural variations in the levels of exposure to the pesticide. Nontarget organisms that associate with the plants, such as birds and insect pollinators, are exposed to a range of such plant-pesticide levels in nature.

EPA also considered the extent to which any substance can be increased in cultivated plants without unwanted effects on other, desirable characteristics of the plant (e.g., yield or palatability of fruit). In general, breeders balance all of these characteristics in developing marketable plant varieties. Considerations of characteristics such as yield could serve to mitigate against exceeding certain ranges of pesticide levels. Agricultural crop plants, those most likely to be grown in large acreages with concomitant large exposures, are not likely to be in the higher portion of the expression range because of these constraints and are not likely to produce as broad a range of levels of plant-pesticides that plants normally produce. EPA anticipates that the majority of agricultural crop plants with modified levels of plant-pesticide expression will fall within existing ranges of pesticide levels and does not anticipate that increasing the level of a plant-pesticide that is normally a component of a plant would lead to a signficantly different spectrum of exposure to the plant-pesticide.

There are also difficulties in establishing what constitutes "significantly higher levels" for regulatory purposes. At the July 13, 1992 meeting, the BSAC Subcommittee was specifically asked and the subcommittee extensively discussed approaches to determining what constitutes significantly higher levels of a plant pesticide. During discussion at the meeting, the BSAC Subcommittee indicated it would be very difficult to establish standards for "significantly higher levels" since no formal complete data base of plant constituents and their concentration ranges exists. Because of these difficulties, the BSAC Subcommittee final report did not suggest a scope criterion based on "significantly higher levels." For these reasons, EPA is not proposing, under FIFRA, to regulate using a criterion based on "significantly higher levels" of a plant-pesticide.

Consistent with the Agency's proposed statement of policy on plant-pesticides, EPA recognizes that plant defense compounds found in plants that are not sexually compatible, or in other organisms such as microorganisms, can be structurally and functionally equivalent to compounds found in the recipient plant or in a plant sexually compatible with the recipient plant. EPA is willing to consider, in the future, exemptions for plant-pesticides (as are proposed for viral coat proteins) if a producer can provide evidence that the plant-pesticide is structurally and functionally equivalent to a plant-pesticide found in the recipient plant or in a plant sexually compatible with the recipient plant. Specifically, the Agency is willing to consider development of procedures and criteria for these plant-pesticides. Please see Request for Comment unit, Unit VII., of this preamble for a fuller discussion of how such exemptions might be granted in future rulemakings.

B. Exemption of Plant-pesticides That Act Primarily by Affecting the Plant

One of EPA's primary goals in regulating pesticides is to control the potential for adverse effects of pesticides on nontarget organisms. An important component in the evaluation of this potential is the way in which the pesticidal substance acts on the target pest since it would also likely affect nontarget organisms through the same mechanism. A pesticidal substance that acts directly on the target pest through a toxic mechanism of action might also exert a similar effect on other organisms. For example, a substance that acts by inhibiting DNA synthesis of the pest could inhibit DNA synthesis in other nontarget organisms.Toxic mechanisms of action include, but are not limited to, those that affect: (i) Membrane permeability, (ii) cell division, (iii) gene expression, (iv) DNA replication, or (v) other metabolic functions (Ref. 3).

Pesticidal substances can also act through mechanisms that are less likely to be directly toxic. Although it is possible for these substances to adversely affect nontarget organisms, the Agency believes that, in most cases, they pose significantly lower levels of environmental risk than plant-pesticides with a generalized toxic mechanism of action. Plant-pesticides that are less directly toxic generally act primarily by affecting the plant so that the pest is inhibited from attaching to the plant, penetrating the plant's surface or invading the plant's tissue. For example, if a plant is modified so that it can counter specific disease-producing compounds by inactivating them, it is less likely that organisms that interact with the plant in other, more beneficial ways will be affected. Similarly, a plant may be modified to produce defense structures such as layers of cork cells in response to infection by fungi or bacteria. These structures form a barrier to further penetration by the pests and may block the spread of any toxins. Other, nontarget organisms that do not stimulate this response are not likely to be adversely affected. The Agency believes that it would be appropriate to exempt from regulation, under FIFRA, plant-pesticides that act through mechanisms such as these. EPA believes that by focusing its regulatory attention on plant-pesticides that act through toxic mechanisms, it will be able to focus on those plant-pesticides presenting higher levels of risk potential. The proposed regulatory text presents criteria to define mechanisms of action that are not directly toxic to the target pest.

EPA proposes that producers would assess whether they meet the criteria presented in the proposed regulatory text. Proving eligibility would rest with the producer claiming the exemption and the producer could meet this responsibility by producing documentation of their determination should a question arise concerning their claim for exemption. If the producer's assessment is incorrect and the plant-pesticide does not qualify for the exemption, anyone selling or distributing the plant-pesticide would be subject to enforcement actions for selling or distributing an unregistered pesticide. Producers would be encouraged to consult with the Agency with regard to specific cases.

EPA is also considering whether to extend this exemption to include substances such as plant hormones because they act by "primarily affecting the plant" and do not act directly on a target pest (see Unit VII.B. of this preamble and the proposed statement of policy published elsewhere in today's issue of the **Federal Register** entitled "Proposed Policy; Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act").

C. Exemption of Coat Proteins from Plant Viruses

Coat proteins are those substances that encapsulate and protect the genetic material of certain viruses. In some cases, when the genetic material encoding for the coat protein is introduced into a plant's genome, the plant is able to resist subsequent infections by the same virus or related strains (termed viral coat protein mediated resistance or vcp-mediated resistance). The Agency is proposing to exempt the genetic material encoding for the coat protein and the coat protein itself when these are introduced into a plant to effectuate viral coat protein mediated resistance.

The Agency's proposal is based on a number of considerations which, when taken together, bring EPA to the conclusion that coat proteins used in vcp-mediated resistance pose low probability of risk and would not cause unreasonable adverse effects. These considerations include the low potential for adverse affects to nontarget organisms and the potential benefits (environmental and economic) of utilizing vcp-mediated resistance.

To promote the fullest discussion of the issue possible, however, the Agency is also offering for discussion an alternative, more limited exemption. The two options are described below followed by an analysis of the options in Unit V.C.3. of this document.

1. *Option 1: Exemption of all coat proteins from plant viruses.* Under EPA's preferred option, all coat proteins from plant viruses (vcp-mediated resistance coat protein) and the genetic material encoding for the coat protein would be exempt from FIFRA requirements when produced in plants for viral coat protein mediated resistance. This exemption would include the regulatory regions and noncoding, nonexpressed sequences needed to introduce the genetic material encoding for the viral coat protein into the plant. This exemption is embodied in the proposed regulatory text.

2. *Option 2: Exemption of coat proteins from plant viruses produced in*

plants with low potential for outcrossing to wild relatives. Under this exemption, the Agency would limit its exemption of vcp-mediated resistance coat proteins to those viral coat protein/plant combinations that would have the least potential to confer selective advantage on free-living wild relatives. The regulatory language defining these viral coat protein/plant combinations would be as follows:

> The pesticidal substance is a coat protein from a plant virus and the genetic material necessary to produce the coat protein has been introduced into a plant's genome, and the plant has at least one of the following characteristics:
>
> (1) The plant has no wild relatives in the United States with which it can successfully exchange genetic material, i.e., corn, tomato, potato, soybean, or any other plant species that EPA has determined has no sexually compatible wild relatives in the United States.
>
> (2) It has been demonstrated to EPA that the plant is incapable of successful genetic exchange with any existing wild relatives (e.g., through male sterility, self-pollination).
>
> (3) If the plant can successfully exchange genetic material with wild relatives, it has been empirically demonstrated to EPA that existing wild relatives are resistant or tolerant to the virus from which the coat protein is derived or that no selective pressure is exerted by the virus in natural populations.

For the purposes of this option, "introduced into the plant's genome" would mean movement of nucleotide sequences into the genetic material in a plant cell's nucleus, mitochondria, chloroplasts, and any other plastids. "Successfully exchange genetic material" would mean capable of forming zygotes viable in the laboratory and/or field through the fusion of two gametes.

Under this option, if a plant is not on the list of plants with no wild relatives in criterion (1), a producer would be required to submit a written request for a determination by EPA as to whether their viral coat protein/plant combination meets criterion (1), i.e., the Agency would have to determine that this particular plant species has no wild relatives in the United States. If criterion (1) could not be met, the producer would have to submit information to the Agency to show that criterion (2) is met or submit empirical evidence that criterion (3) is met.

3. *Analysis of options.* The Agency's preferred option of exempting all vcp-mediated resistance coat proteins is based on the limited potential for adverse effects to nontarget organisms and/or new exposures to the coat protein and the potential environmental and economic benefits from using vcp-mediated resistance.

Environmental benefits associated with the use of viral coat proteins include the reduction of the use of chemical pesticides for viruses that are spread by vectors (usually insects). Chemical pesticides are used for those crop plants where the most effective method of protection against viral attack is by controlling the vector. These pesticides may not be environmentally benign. The expression of viral coat proteins by plants for protection from viral infection would likely reduce the amount of chemical pesticide used to control the vectors.

In addition to environmental benefits associated with the use of viral coat proteins, an effective method for controlling virus infection will have economic benefits. Plant viruses create economic losses for a vast variety of crops by reducing yields and negatively affecting the quality of the crop. Yield losses and quality effects for a specific crop may vary depending on the host plant and strains of the virus present, the incidence and activity of vectors, timing of the infection, health and nutritional state of the plant, and weather (Ref. 5).

Presently, growers may need to use several control methods during a crop season in an attempt to prevent viral infection and dissemination, primarily by planting virus free material (for mechanically transmitted viruses) and by controlling plant virus vectors, such as insect populations (for vector transmitted viruses). Insecticides, nematicides, and fungicides are all used for vector control with varying success, depending upon the virus/vector relationship and vector efficiency. Plants developed through conventional breeding techniques offer some degree of virus resistance. Such resistance may not be uniform or the virus may develop new strains. However, breeding for resistance has not been successful for the majority of field crops and, in particular, vegetable crops that are severely affected by viruses (Ref. 6).

In enabling plants to resist viral attack, viral coat proteins act in a very specific fashion, apparently adversely affecting only viruses by blocking or limiting their ability to infect, replicate, and/or translocate within the plant. This specificity minimizes the potential for viral coat proteins produced in plants to adversely affect nonviral organisms. In addition, plants in nature and in the agro-ecosystem frequently exhibit viral infections; nontarget organisms, including humans, have been and continue to be exposed to the viral coat proteins with no observed adverse effects.

The possibility that environmental risk might be associated with the use of vcp-mediated resistance was discussed at the December 18, 1992 FIFRA Scientific Advisory Panel (SAP) Subpanel meeting (see Unit VI. of this preamble for a more thorough discussion of the issues discussed by EPA's science advisory committees). EPA agrees with the conclusions of the SAP Subpanel and in developing its proposal has utilized the advice of the Subpanel to supplement EPA's own evaluation of the scientific literature (Ref. 2). The considerations discussed by the Subpanel included: (1) The potential for new viruses to be formed through transcapsidation (also called heterologous encapsidation) and recombination, (2) the potential for synergistic infections, (3) the potential for seed transmission, and (4) the potential for the development of selective advantage in wild relatives through successful hybridization with the plant producing the viral coat protein. The SAP Subpanel report offered advice on these potential risk considerations and this advice is incorporated into the discussion below.

Most plant viruses are composed of genetic material enclosed in a protein coat. For these viruses, the coat protein is the site of interaction with the host plant at several stages of the viral cycle (e.g., virus replication and movement within the plant). The coat protein also plays an essential role in transmission by vectors such as insects.

The issue of transcapsidation revolves around the question: if a plant that produces a vcp-mediated resistance viral coat protein from Virus A is infected by Virus B, can the Virus B genome be encapsidated by the Virus A derived vcp-mediated resistance coat protein synthesized by the plant? The consequence of such transcapsidation is the possible extension of the host range of the virus through the possible transmission of the Virus B genetic material by vectors that would not normally transmit Virus B and possible infection of plants that would not normally be exposed to and/or infected by virus B.

Heterologous encapsidation or transencapsidation has been observed both *in vitro* and *in vivo* between coinfecting whole viruses. However, transencapsidation between coinfecting viruses occurs more frequently between related viruses than unrelated viruses. Although some researchers have examined this question, there is no evidence that transencapsidation involving vcp-mediated resistance coat proteins produced in plants would occur at a higher frequency than has

been observed with coinfecting whole viruses.

With regard to transencapsidation involving vcp-mediated resistance coat proteins and horizontal transmission, the SAP Subpanel concluded that transencapsidation and transmission to other plants would most likely occur at low levels or would not occur, depending on: (1) The level of vcp-mediated resistance coat protein being produced by the plant (larger concentrations of vcp-mediated resistance coat protein would increase the probability of transcapsidation); (2) the efficiency of transencapsidation (this varies for transencapsidation of whole viruses); and (3) the efficiency of virus acquisition by the virus vector. For viruses in which a specific protein-RNA-helper factor complex is essential for transencapsidation or transmission to occur, transmission is virtually impossible.

With regard to the potential for recombination between the plant-encoded coat protein and coat protein from an infecting virus different from the virus contributing the coat protein gene, the consequence of such recombination is the potential for the formation of a new virus. The December 18, 1992, SAP Subpanel concluded that recombination is not a risk consideration meriting regulatory oversight. Most recombination events demonstrated to date involve either a debilitated virus under strong selection pressure for restoration of the wildtype virus, or the exchange of terminal regulatory sequences. In both conditions, recombination was only demonstrated between very similar or identical viruses. New viruses are thus unlikely to arise through a recombinational event involving substitution of the vcp-mediated resistance coat protein genetic material for the coat protein genetic material of the infecting virus. Should variants of a virus arise through recombination, these variants would be subject to selection/competitive pressures throughout the infection cycle as are variants that arise from recombination between replicating viruses. In addition, there is no evidence that recombination between plant-produced coat proteins and an infecting virus would occur at greater frequencies than currently occur in nature between replicating viruses.

Synergistic-infection occurs when two viruses infect the same plant, causing more severe damage than would occur if either virus alone infected the plant. With regard to the potential for synergistic-infection, the SAP Subpanel stated that plants expressing Virus A vcp-mediated resistance coat proteins do not express a synergistic response when the plant is inoculated with Virus B that potentially could act synergistically with Virus A, either because coat proteins are not involved in synergy, or because the level of expression of the protein is too low to potentiate the interaction.

In some species of plants, infecting viruses can be transmitted vertically to progeny plants through seed. The question posed with vcp-mediated coat proteins is whether their presence in the plant might affect seed transmission of infecting viruses. With regard to the possibility of coat protein modifications affecting the ability of seed to transmit viruses, the SAP Subpanel report states that in two cases where the viral genetics of seed transmission of viruses has been analyzed, genes other than those encoding the coat protein genes are involved in potentiating the transmission. There is no reason *a priori* to believe that introduction into the plant of viral coat protein genes would affect the level of vertical transmission of viruses through seed.

The possibility that transfer of the vcp-mediated resistance coat protein gene to a wild relative of the modified crop plant might bestow a selective advantage on the wild relative has also been examined by the SAP Subpanel and the Agency. The SAP Subpanel report indicates that even if the low probability events of transfer and expression of the coat protein gene from crop plant to wild relative occur, the wild plant may not acquire a selective advantage. The Subpanel report noted, however, that while the series of events that must occur for the wild plant to acquire a selective advantage is rather improbable, such a series of events is not impossible.

To address this possibility, the Agency is offering an alternative option that is a more limited exemption of vcp-mediated resistance coat proteins. For this alternative option, the Agency has defined a set of criteria and a process that would be used to identify those viral coat protein/plant combinations that have the greatest potential to outcross to wild, free-living relatives and thus have the possibility to endow these wild relatives with a competitive advantage. Viral coat proteins that potentially could be outcrossed would be subject to regulation. Those viral coat protein/plant combinations with a lesser or no probability of outcrossing and thus having a lesser or no probability of resulting in selective advantage would be exempt from regulation. An example of the latter situation would occur when a plant has no wild relatives in the United States or, if it has such relatives, cannot exchange genetic material with any of them. Under such circumstances, there is no opportunity for selective advantage through acquisition of the gene encoding the viral coat protein to occur in the wild relative since successful genetic exchange would not occur.

It should be noted that neither of the exemptions described by Option 1 nor Option 2 for viral coat proteins extends to other methods used to create viral resistance in plants, such as the introduction of the gene encoding for RNA replicase or the introduction of genes encoding for satellite RNA (supernumary RNA with essentially no sequence similarity with the host virus) into plants. EPA does not believe it should exempt satellite RNA since single nucleotide base changes have been shown to significantly alter the characteristics of satellite RNAs including turning a nonnecrogenic satellite into a necrogenic satellite. At this point, the Agency is only proposing an exemption for vcp-mediated resistance coat proteins from plant viruses.

EPA prefers Option 1 for a number of reasons. EPA believes that the use of vcp-mediated resistance represents little potential for adversely affecting nontarget organisms and has a low potential for other environmental risks even in the absence of any regulatory oversight under FIFRA. In addition, vcp-mediated resistance is associated with potential environmental benefits such as decreased use of chemical pesticides and economic benefits to farmers and society because it represents a means of controlling losses to viral disease in the absence of effective alternative methods to control viral infection. Option 1 represents a clearer regulatory line than Option 2 in terms of which plant-pesticides will be regulated under FIFRA. Option 1 is more consistent with the approach taken for plant-pesticides under FFDCA. Option 1 allows the Agency to focus on plant-pesticides posing higher potential risks. In addition, under the Plant Pest Act, USDA/APHIS addresses the potential for selective advantage among wild plants in its review of plants genetically engineered to produce viral coat proteins.

At the January 21, 1994 joint SAP/Biotechnology Science Advisory Committee (BSAC) meeting (see Unit VI of this preamble), the alternative option (Option 2) for the exemption of viral coat proteins was discussed. The joint Subpanel agreed that Option 2 created a process to address the possibility of selective advantage being acquired by a wild relative through outcrossing of the

vcp-mediated resistance coat protein gene from the modified crop plant. However, the joint Subpanel did not believe that there was a high enough level of concern to warrant the inclusion of this option.

The report of the January 21, 1994 meeting summarizes that: (1) Wild relatives are not found growing near many of the important crop plants grown in the United States; (2) criteria 2 and 3 of the alternative option address extremely rare situations, the existence of which would be very difficult to completely disprove; (3) the potential for increasing the ability of wild relatives to resist viral infection is likely to be beneficial because it could lead to a reduction of the reservoir for plant viruses; and (4) the use of vcp-mediated resistance is more "environmentally friendly" than the application of chemical pesticides to control virus vectors.

The Agency's preferred option would be to completely exempt vcp-mediated coat proteins from FIFRA regulation. Because of the potential benefits and the low probability of risks from the use of vcp-mediated resistance coat proteins in plants, EPA believes they warrant exemption under FIFRA 25(b) as being "of a character that is not necessary to be subject to the Act." In addition, USDA/APHIS's review of field testing of plants genetically engineered to produce vcp-mediated resistance proteins addresses the possibility that the use of vcp-mediated coat proteins may create some potential for a selective advantage to be acquired by wild plants as well as the possibility of creating new viruses through recombination and/or transencapsidation.

EPA is aware that, in addition to viral coat proteins, there are viral components such as viral movement proteins and viral replicase that are being tested for virus resistance strategies in plants. Many of the risk issues considered by EPA for viral coat proteins may be similar to those most likely to be addressed when examining the risks that could potentially be associated with the use of other viral components. USDA/APHIS's review of plants genetically engineered to produce viral coat proteins addresses such potential risks. EPA is committed to minimizing duplicative review of products between Federal agencies and is also committed to developing an appropriate regulatory approach for biologically-based pesticides in general, potentially including pesticides based on viral components produced in plants. EPA would tailor its regulatory procedures according to the biological characteristics of these products. These procedures could, for example, include expedited procedures for registration, the development of performance-based criteria for exemptions, and specific product exemptions. For example, the exemption of plant-pesticides that "primarily affect the plant" could be extended in the future, through the inclusion of an additional criterion, to include viral components that are used in viral resistance strategies in plants when they affect the plant so that the viral pest cannot invade the plant.

VI. External Review

In developing its approach to regulating plant-pesticides, EPA has requested the advice of two scientific advisory committees at three meetings. On December 19, 1992, pursuant to section 25 of FIFRA, a Subpanel of the FIFRA SAP was convened to review a draft policy statement on plant-pesticides and respond to a series of scientific questions posed by the Agency primarily on EPA's approach under FIFRA. On July 13, 1993, a Subcommittee of the EPA BSAC was convened to address a series of scientific questions primarily on EPA's approach under FFDCA. On January 21, 1994, a joint meeting of a SAP/BSAC Subpanel on plant-pesticides was held. The issues raised at these meetings are discussed below, together with the Agency's response. (Full reports from these meetings are available in the public docket.)

A. Substances New to the Plant

Questions on how best to describe "substances that are new to the plant" were posed at all three science advisory meetings. At its December 1992 meeting, the FIFRA SAP Subpanel was asked whether the taxonomic demarcation of "genus" was appropriate, or whether some other demarcation would be more appropriate. The Subpanel expressed concern over an exemption based on a taxonomic definition and suggested the Agency evaluate a series of considerations involving the potential for quantitative and qualitative differences in exposure to a plant-pesticide.

The SAP Subpanel suggested that the Agency would "need to create a workable balance between effective regulatory oversight and encouragement of the development of plant-produced pesticides."

At its July 13, 1993 meeting, the BSAC Subcommittee addressed a related issue with regard to the regulation of plant-pesticides under the FFDCA and human dietary exposures to plant pesticides.

Included in questions to the Subcommittee were queries on the availability of information on current levels of exposure in the diet to plant-pesticides in raw agricultural commodities and on which plant-pesticides might be of concern should their levels be significantly increased.

The BSAC Subcommittee in their report stated that no formal, complete data base for such information exists. Rather most of this knowledge is part of breeders' experience, with breeders depending primarily on familiarity with food crops (e.g., knowledge of which crop plants have the ability to produce which toxicants) to ensure consumers are not exposed to deleterious levels of such substances. In general, little information exists on the range of levels of plant-pesticides in plants, including ranges within the most studied grouping, food plants. The mechanisms through which plants display resistance to pests, moreover, have not been well worked out. Based on experience, however, the BSAC Subcommittee suggested EPA consider a scheme based on sexual compatibility to identify those groupings wherein plant-pesticides might present new and novel dietary exposures and those that would not.

The use of sexual compatibility and/or taxonomy as a standard for the potential for significantly different environmental exposures was discussed at the January 21, 1994, joint SAP/BSAC Subpanel meeting. The panel members were supplied with the reports of the previous meetings and drafts of proposals analyzing the strengths and weaknesses of approaches based on sexual compatibility and/or taxonomy. In response to the question of whether plants in a sexually compatible population are likely to share substances or traits, the joint Subpanel agreed that sexually compatible plants are more likely to have a common constitution than unrelated plants and thus movement of genetic material between sexually compatible plants is less likely to lead to novel exposures. Natural hybridization and selection have produced groups of plants which have a common gene pool. Generations of artificial hybridization to produce improved cultivated plants have tended to increase the extent of relatedness among elements of a broader segment of the natural diversity. In addition, modern techniques of genetic mapping have revealed the presence of genetic loci in cultivated plants that previously were considered to be present only in the wild species.

In regard to the correlation of the concept of "genus" with significantly different environmental exposures, the

panel noted that the taxonomic classification of a genus and the measure of sexual compatibility are closely interrelated. Sexual compatibility tends to promote genetic interchange and this interchange leads to populations of plants more like each other than like groups that have been sexually isolated. Because plants in the same genus likely have common ancestors that at some period in their evolution were sexually compatible, plants in the same genus are more apt to be sexually compatible with each other than with plants from other genera. Some barriers to sexual compatibility exist between species in the same genus even though the species are similar taxonomically. However, many of these sexual barriers can be overcome through the use of wide cross techniques by breeders.

The report of the January 21, 1994, joint SAP/BSAC Subpanel meeting, indicates that the joint Subpanel agrees that basing an exemption on both the concept of sexual compatibility and the concept of taxonomy should restrict the occurrence of significantly different exposures and finds that Option 3 is a reasonable approach for agricultural plants. However, the joint Subpanel questioned whether an assumption of low probability of novel exposures can be extended to wild or semi-wild plants. For these types of plants, the genus standard "in particular," may result in the exemption from regulation of plant-pesticides that may present novel exposures.

The Agency also included a question, at the January 21, 1994, joint BSAC/SAP meeting, concerning an approach using a criterion based on the process used to modify the plant, e.g., recombinant DNA methodologies. As described in the report of the joint BSAC/SAP Subpanel meeting, if the Agency were to use this approach, it would first exempt plant-pesticides developed through techniques other than those of modern biotechnology from its regulatory scope. For those plant-pesticides that are *not* exempted because they were developed through techniques of modern biotechnology, the exemptions proposed by the Agency would apply (i.e., the exemption based on plants' relatedness and the exemption of plant-pesticides that act by "primarily affecting the plant"; see Units V.A. and V.B. of this preamble).

The joint Subpanel supported the inclusion of an option using a criterion based on methodologies such as rDNA as a rational approach to making the first cut as to which plant-pesticides would be regulated. However, the joint Subpanel cautioned that further exemptions such as those proposed by EPA should be used in conjunction with the criterion based on methodology. In addition, the joint Subpanel recommended that the Agency define methodologies in a way that clearly delineates to the scientific community and the public what is and is not included in the regulatory scope, based on current state-of-the science.

EPA Response: The Agency has chosen to propose to use under both statutes, an approach based on sexual compatibility. First, this approach would exempt under both FIFRA and FFDCA, plant-pesticides having a high probability of being derived from plants having high numbers of genes in common. Under such circumstances, the likelihood of new or novel exposures both to the environment and in terms of human consumption is low.

Second, use of the standard of sexual compatibility is the preferred option under both FIFRA and FFDCA and would allow EPA to use its authorities under FIFRA and FFDCA in concert to regulate plant-pesticides, and thus to utilize, to the extent possible in light of the different statutory standards, similar approaches to oversight under each of the two statutes.

Third, the Agency believes that its proposed approach would be consistent with the December 1992 SAP Supbanel's concern that EPA ". . . create a workable balance between effective regulatory oversight and encouragement of the development of plant-produced pesticides." Under the preferred approach, novel exposures are not likely to occur with plant-pesticides exchanged between plants that are sexually compatible (See also Unit V. of this preamble for additional discussion).

With regard to the advice of the January 21, 1994, joint SAP/BSAC Subpanel concerning the use of a process-based criterion in the scope, if the Agency were to use this approach, plant-pesticides developed through techniques other than those involving *in vitro* manipulation of genetic material would be exempt. In order to meet the recommendations of the joint Subpanel, the Agency would define this category of plant-pesticides in the following way: The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is extracted from an organism and introduced into the genome of the recipient plant or is synthesized *in vitro* and introduced into the genome of the recipient plant. The exemptions proposed by the Agency in Unit V. of this preamble would be used in concert with this criterion. The Agency believes this approach would meet the recommendations of the SAP/BSAC joint Subpanel. The Agency is soliciting comment on this approach (see Unit VII.A. of this preamble).

B. Plant-pesticides That Act Primarily by Affecting the Plant

The SAP Subpanel at its December 1992 meeting considered whether EPA's language clearly and sufficiently identified plant resistance mechanisms that do not involve substances whose mode of action produces a direct toxic effect on the pest. The SAP Subpanel stated that for the most part the language EPA was proposing was clear and appropriately identified plant resistance mechanisms whose mode of action was not directly toxic. The Subpanel noted, however, that the issue of resistance to toxins produced by the pests was not addressed by that language. The Subpanel recommended insertion of the following statement into EPA's proposed language: "Acts in the host plant to produce target(s) of the toxin that are resistant to the toxin's deleterious action."

EPA Response: EPA accepted this recommendation and modified the language of its approach to incorporate the issue of resistance to toxins.

C. Viral Coat Proteins

The December 18, 1992, SAP Subpanel meeting and the January 21, 1994, joint SAP/BSAC Subpanel meeting addressed the use of viral coat protein genes to modify plants to protect the plant from damage from viral infection. In the discussion at the December 18, 1992, SAP Subpanel meeting, several risk considerations were identified and the probability of occurrence of each addressed in the SAP Subpanel report. The SAP Subpanel report stated that the probability of occurrence of the risks examined is very low. The January 21, 1994, joint SAP/BSAC Subpanel meeting discussed the alternative option for the exemption of viral coat proteins from FIFRA regulation. The joint Subpanel did not believe that the potential risks associated with the use of vcp-mediated resistance coat proteins warranted inclusion of the alternative option. Unit IV.C.3. of this document describes how the SAP and joint SAP/BSAC discussion of vcp-mediated resistance viral coat proteins supplements and influences EPA's analysis.

EPA Response: EPA agrees that the probability of risks from the introduction of viral coat protein genes into plant genomes is low, and as its preferred option proposes to exempt these plant-pesticides from FIFRA

oversight. Because of public comments received at the December 18, 1992, SAP Subpanel meeting and the January 21, 1994, joint SAP/BSAC meeting, however, concerning viral coat protein and selective advantage to wild relatives of managed plants, EPA is offering for comment in this proposal the alternative approach to viral coat proteins to allow the fullest discussion possible.

D. U.S. Congress and U.S. Department of Agriculture

In accordance with FIFRA section 25, a draft of this proposed regulation and a draft of the statement of policy published elsewhere in today's issue of the **Federal Register** entitled "Proposed Policy; Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act" (proposed policy statement) was submitted in June 1994, to the U.S. Congress and USDA. USDA provided written comments on these two drafts on August 18, 1994. These comments are discussed below together with EPA's response.

1. USDA suggests that the exemption EPA is proposing under FIFRA for viral coat proteins should be extended to include all plant viral proteins used in viral resistance strategies and the viral genetic sequences that encode them (including antisense constructs).

EPA response: While EPA does not believe that, at this time, it can exempt all viral components from regulation under FIFRA it has requested comment on such an exemption. EPA is committed to minimizing duplicative review and would develop a coordinated approach with USDA for viral-based products other than viral coat proteins. As the experience base grows for these products, the two agencies can develop a regulatory course that is mutually acceptable. These procedures could, for example, include expedited procedures for registration, the development of performance-based criteria for exemptions, and specific product exemptions.

2. USDA suggested that ambiguity exists in the use of the term "user" in the discussion on informational labeling for plant-pesticides in the proposed policy statement.

EPA Response: EPA agrees that this discussion in the proposed policy statement may be ambiguous and proposes to replace the term "user" with the term "farmer and grower."

3. USDA noted that EPA's exemption based on the premise that plant-pesticides derived from sexually compatible plants would not result in new environmental exposures does not take into account that similar or equivalent genes can be found in plants that are not sexually compatible.

EPA's Response: EPA recognizes that plant defense compounds found in plants that are not sexually compatible, or in other organisms such as microorganisms, can be structurally and functionally equivalent to compounds found in the recipient plant or in a plant sexually compatible with the recipient plant. The Agency is willing to consider development of procedures and criteria for these plant-pesticides. A discussion of these procedures and criteria can be found in the Request for Comment unit, Unit VII., of this preamble.

4. Although not included in USDA's written comments, USDA suggested, in a discussion at an August 18, 1994 meeting between USDA and EPA representatives, some clarifications in the discussion on plant regulators and plant hormones in the proposed policy statement. USDA indicated that there was some ambiguity as to how EPA would regulate plant hormones under FIFRA.

EPA Response: EPA agrees that the plant regulator discussion may lead to some confusion as to how EPA would regulate plant hormones. EPA has agreed to include a discussion in the section on plant regulators in the proposed policy statement that would more fully describe the status of these plant-pesticides in relation to the proposed exemption of plant-pesticides derived from sexually compatible plants or under the proposed exemption of plant-pesticides that ". . .primarily affect the plant. . ." (see Unit IV.D.in the proposal published elsewhere in today's issue of the **Federal Register** entitled "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule").

VII. Request for Comment

The Agency requests comments on the proposed exemptions of plant-pesticides under FIFRA.

A. Exemption of Plant-pesticides Derived from Closely Related Plants

1. *Three options.* EPA requests comment on whether the Agency has appropriately identified in this proposed exemption (see Unit V.A. of this preamble) those plant-pesticides that are not likely to result in significantly different environmental exposures. EPA requests comment on its three options, specifically as to whether the options appropriately identify plant-pesticides that would not result in significantly different exposures to nontarget organisms and whether the language the Agency uses in the options clearly circumscribes the appropriate groupings. EPA requests comments on which option is most appropriate and why.

2. *Criterion based on process.* With regard to an exemption criterion based on the process used to modify the plant, the Agency is soliciting comment on the joint BSAC/SAP Subpanel advice and the utility of an approach based on that advice (see Unit VI. of this preamble). EPA also requests comment on whether the group of plant-pesticides that would be regulated under this approach would be equivalent to the group of plant-pesticides that would be regulated under Options 1, 2, or 3.

3. *Equivalent plant-pesticides.* As described in Unit V.A.6. of this preamble, EPA is considering the development of procedures and criteria for how EPA can exempt a plant-pesticide if a producer can provide evidence that the plant-pesticide is structurally and functionally equivalent to a plant-pesticide found in a recipient plant or in a plant sexually compatible with the recipient plant. To effect such rulemaking, the Agency would need to meet statutory standards under FIFRA. In the instance of plant-pesticides, EPA would need, for example, to determine whether a plant-pesticide is indeed structurally and functionally equivalent to a plant-pesticide that has been exempted.

Under such a rulemaking effort, a producer would provide information to the Agency showing that a plant-pesticide meets the standard for exemption under FIFRA. The Agency would respond, within a limited period of time, to the producer as to whether the plant-pesticide meets that standard. The Agency envisions that producers would have a fairly high degree of latitude in types of specific data that could be used to demonstrate that a plant-pesticide meets the standard for exemption.

The Agency is requesting comment on this framework for the exemption rulemakings. In particular, the Agency is soliciting comment and information on whether to incorporate specific data requirements/methodologies into exemption criteria and on appropriate time-frames for the Agency determinations.

The main challenge for EPA in engaging in such future rulemakings will be to develop criteria that can be used to create a standard for what constitutes equivalency. There are a number of different approaches that EPA believes it could utilize. The following discussion describes these approaches and some of the strengths and weaknesses of these options. The

Agency requests comment on these approaches and solicits suggestions on additional factors that the Agency should weigh in the development of criteria for equivalency.

In developing criteria for exempting a plant-pesticide from FIFRA, the first consideration for EPA is what parameters, in general, are good measurements for equivalency of function. The next consideration for the Agency in the development of criteria for creating exemptions is to examine these parameters in light of what is known concerning the characteristics of plant defense mechanisms.

Turning first to the general parameters, some examples of the types of parameters that the Agency could use in developing criteria for proteinaceous substances are amino acid sequence homology, posttranslational processing, structure, stability, receptor/ligand specificity, and substrate specificity. For nonproteinaceous substances, equivalence in chemical composition and structure are additional examples of parameters that could be used as the basis for developing criteria.

Any measures of equivalence that the Agency chooses to adopt should be applicable to particular plant-pesticides that may operate by a variety of mechanisms. The Agency requests comment on how evidence of structurally homology for proteinaceous defense compounds could be used in the future as reliable predictors of functional homology. Would it be more appropriate to develop an approach that does not rely soley on percent amino acid sequence homology but also incorporates the identification of conserved and variable amino acid sequences? For example, it is postulated that some disease resistance genes encode transmembrane receptors. Might sequences such as those involved in transmembrane interactions then be identified to provide additional assessment of equivalent function?

A number of enzymes such as glucanase, chitinase, and proteinase inhibitors are also thought to be involved in plant defense responses. The question then arises as to whether a chitinase from, for example, tobacco or a microorganism is equivalent to a chitinase found in a plant sexually compatible with the recipient plant. As in the previous example, amino acid sequence homology could also assist in establishing equivalency for these enzymes. However, as with the previous example, the question of how much homology is sufficient remains. Would a better measurement be to use stability, substrate specificity, K^m, and V^{max}? Should these parameters be used in conjunction with homology?

Nonproteinaceous compounds such as phenolics and phytoalexins are another class of plant defense compounds. For nonproteinaceous compounds structure/activity comparisons can be used to determine functional equivalence. For example, the presence of specific side chains could be used to establish equivalence. Other parameters such as stability could also be used. The question for the Agency is what amount/combinations of information would be necessary to use as a measure of equivalence..

B. Exemption of Plant-pesticides that Act Primarily by Affecting the Plant

With regard to its exemption from FIFRA requirements of "plant-pesticides that act primarily by affecting the plant," EPA requests comment on whether this exemption appropriately focuses the Agency's regulatory attention on the plant-pesticides likely to present higher levels of hazard. The Agency also requests comment on whether the language defining this exemption is sufficiently clear and inclusive to identify plant-pesticides that act through nontoxic modes of action.

The Agency is considering whether to extend this exemption to include substances such as plant hormones because they primarily affect the plant and do not have a directly toxic mechanism of action toward the target pest. The Agency is requesting comment as to whether it would be more appropriate to specifically exempt plant hormones as a category or to include in this exemption a performance-based criterion based on a description of the characteristics and/or mechanism of action of hormones (see Unit V.B. of this preamble).

C. Exemption of Coat Proteins from Plant Viruses

EPA is also proposing to exempt from FIFRA regulation, coat proteins from plant viruses when the coat proteins are produced in plants. EPA has proposed two options for this exemption with Option 1 presented in the proposed regulatory text. EPA is requesting comment on the appropriateness and clarity of the two options presented in this proposal. EPA is also requesting comment on: (1) The potential for the recipient crop plant producing the viral coat protein to become a weed; (2) the potential for increased competitive advantage of wild relatives in their native habitat after cross hybridization with a crop plant producing a viral coat protein; and (3) the potential for a viral coat protein gene to recombine with infecting viruses to extend host range or create new virus diseases.

EPA is considering whether to propose in the future, an exemption of viral components, other than viral coat proteins, used in viral resistance strategies in plants. This exemption would include performance-based criteria that would be used by EPA to determine if a viral component would be exempt from regulation. EPA is requesting comment on whether such an exemption would be appropriate and is requesting comment on criteria that could be used to construct this exemption.

D. Substantiation of Claims for Confidential Information

EPA requests comment on the proposed requirement (§ 174.9 of the regulatory text) that any claim of confidentiality must be substantiated at the time the claim is made. Specifically, EPA seeks comment on how to achieve the best balance between the burden on industry to provide substantiation before public disclosure becomes an active issue (e.g., in preparation for FIFRA Science Advisory Panel meetings) and the regulated community's desire to receive timely responses on submissions. This balance must take into consideration the needs of pesticide developers to protect information they believe to be critical to maintaining their competitiveness and the public's need for access to information related to potential environmental or human health effects early enough in the review process to provide informed comment before EPA makes a decision. EPA encourages the development of reduced risk pesticides and believes that, given the Agency's procedural requirements for CBI determinations, without up front substantiation, timely responses to subsmissions would be difficult when it becomes necessary to resolve the issue of CBI before a decision can be made.

VIII. Economic Analysis

The regulatory impact analysis (RIA) evaluates the costs and benefits of amending EPA's regulations to allow for the regulation or exemption of specific types of plant-pesticides under FIFRA (40 CFR 152.20 and 40 CFR part 174) and is intended to meet the requirements for a RIA as established by Executive Order No. 12866, the Regulatory Flexibility Act, and section 25 of FIFRA.

The RIA presents the alternative regulatory options and the costs that were considered by the Agency including two options that were

considered by the Agency but not included in this proposal. Four possible approaches to the regulation of plant-pesticides under FIFRA were evaluated in the RIA that allowed for varying degrees of regulatory coverage. RIA Option 1 is the most limited alternative in regulatory scope. RIA Option 2 represents EPA's proposed, and preferred, regulatory scope and is broader in coverage than RIA Option 1. In addition to those plant-pesticides regulated under RIA Option 2, RIA Option 3's scope would include viral coat proteins used as plant-pesticides. Finally, under RIA Option 4, all plant-pesticides, including those that result from traditional plant breeding, would be subject to the requirements of FIFRA. The costs of implementing the four options presented in Unit IV.A. of this preamble are comparable to each other and correspond to RIA Option 2. The costs for any of the four options presented in Unit IV.A. are substantially lower than RIA Option 4.

Generally, costs will depend on whether the Agency exempts a plant-pesticide or whether it requires a registration. The costs of regulating plant-pesticides are dependent upon the data needed for the registration of the particular types of plant-pesticides. Data needs are irrelevant for exempted plant-pesticides. For regulated plant-pesticides, data needs will vary according to the gene product of the plant-pesticide and the recipient crop.

Aggregate incremental compliance costs to the industry over a 10–year period under regulatory (RIA) Option 1 are estimated to range from $53,700 in the first year of implementation to $2.6 million in the 10th year of implementation, with an average annual revenue requirement (ARR) of $1.2 million. Under EPA's proposed scope (RIA Option 2), aggregate incremental compliance costs are predicted to range from $53,700 in year 1 to $3.1 million in year 10, with an ARR of $1.6 million. Aggregate incremental compliance costs for RIA Option 3 are estimated at nearly $741,100 in the first year of implementation and $5.1 million in the 10th year, with an ARR of $2.9 million. Finally, under RIA Option 4's broad regulatory scope, aggregate incremental compliance costs are projected to range from $76.6 million in year 1 to $81 million in year 10, with an ARR of $79 million.

Costs were also estimated for the labor burden that would result from EPA staff preforming various activities associated with the registration of plant-pesticides. Some of these activities may include the establishment of the docket, internal reviews, requests for additional information, and consultations with applicants. The cost for the Agency to perform these activities under RIA Option 1 is estimated to range from nearly $40,000 in year 1 to approximately $259,000 in year 10. Under EPA's proposed regulatory scope, RIA Option 2, annual labor burden costs range from approximately $40,000 in the first year to $391,000 10 years after a final rule is promulgated. For RIA Option 3, EPA costs are estimated to range between $123,000 in year 1 to $640,000 in year 10. Under the broad regulatory scope of RIA Option 4, EPA's labor costs are predicted to range between $14.7 million in year 1 to $15.2 million in year 10. Labor burden cost estimates vary by year, due to the number and type of plant-pesticide submissions the Agency is predicted to receive.

The aggregate cost to society of the proposed plant-pesticide regulation is the sum of the total costs to industry, plus the total costs to the Agency to implement the proposed rule. After calculating aggregate societal costs, they were discounted to allow for the time value of money and to determine a constant level annual cost. The annual societal revenue requirement over the 10–year period of analysis was estimated at nearly $1.4 million under RIA Option 1, $1.8 million under RIA Option 2, $3.3 million under RIA Option 3, and $93.7 million under RIA Option 4.

Primarily affected by this proposed regulation will be those companies involved with agricultural biotechnology that have been identified as presently developing and testing plant-pesticides. While agricultural biotechnology is currently in its infancy with 1993 sales estimated at less than 2 percent of total biotechnology sales, future sales are forecasted to grow at an average annual rate of 33 percent to the year 2003. Firms developing biotechnology products are quite diverse and include large, multinational corporations, biotechnology companies (both large and very small), chemical companies, and seed companies. The impacts of EPA regulation of plant-pesticides to this growing market sector will not be all negative. Companies involved with agricultural biotechnology have asked for plant-pesticide regulations and they stand to benefit tremendously from this proposed regulation.

The proposed rule will generate a wide range of benefits for the public, the firms involved with agricultural biotechnology, the environment, nontarget organisms, and states. Registrants of plant-pesticides should benefit from the resolution of uncertainty regarding regulatory issues. With the promulgation of the proposed regulation, firms developing and testing plant-pesticides can plan ahead for timely product development and commercialization which should, in turn, attract investors to the agricultural biotechnology sector. The environment will benefit from safety measures that will protect against unintended environmental effects of accidental and deliberate releases of genetically engineered organisms. Nontarget organisms, including endangered species, will benefit from a registration process that will carefully consider the potential effects that certain plant-pesticides may have upon them. Finally, states will benefit by having a set of standardized Federal regulations that will be more easily conveyed, interpreted, and enforced. Many states may also benefit by not having to establish their own set of agricultural biotechnology regulations.

Adverse economic impacts from the implementation of the proposed plant-pesticide regulation are not expected under EPA's proposed scope (RIA Option 2). Due to the lack of detailed financial information on those firms that are currently developing and testing plant-pesticides, the conclusion of "no adverse economic impacts" was based on public and proprietary information provided to EPA by industry financial advisory groups, biotechnology associations, university biotechnology specialists, and small biotechnology firms.

IX. Public Record

EPA has established a public record for this rulemaking (docket control number OPP–300369). The record includes all information considered by EPA in developing this proposed rule. The record now includes the following items:

1. Reports of all SAP and BSAC meeting pertaining to this proposed rule.

2. Support documents and reports, including:

(a) EPA issue paper. FIFRA: Benefit and environmental risk considerations for inherent plant-pesticides.

(b) EPA issue paper. Issues associated with the regulation of viral coat proteins under FIFRA and FFDCA.

3. Published literature that is cited in this document.

4. The Regulatory Impact Analysis for this rule.

5. Records of communications between EPA personnel and persons outside EPA pertaining to the development of this proposed rule.

(This does not include any inter- or intra-agency memoranda, unless specifically noted in the Index of this docket.)

X. References

(1) EPA issue paper. FIFRA: Benefit and environmental risk considerations for inherent plant-pesticides.

(2) EPA issue paper. Issues associated with the regulation of viral coat proteins under FIFRA and FFDCA.

(3) Klaasen, C.D., M.O. Amdur, and J.D. Doull. 1986. Casarett and Doull's Toxicology: The Basic Science of Poisons. Chapter 2. Third Edition. Macmillan Publishing Company, New York.

(4) Lamb, C.J., J.A. Ryals, E.R. Ward, and R.A. Dixon. 1992. Emerging strategies for enhancing crop resistance to microbial pathogens. Bio/Technology. 10:1436–1445.

(5) Matthews, R.E.F. 1981. Plant Virology. Chap. 17. Second edition, Academic Press, New York.

(6) Tolin, S.A. 1991. Persistence, establishment, and mitigation of phytopathogenic viruses. In: Risk Assessment in Genetic Engineering. Edited by M.A. Levin and H.S. Strauss. McGraw Hill, Inc., New York. pp. 140–161.

XI. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the proposed regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the Order defines a "significant regulatory action" as an action that is likely to result in a rule (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this proposed rule is a "significant regulatory action" because it raises novel policy issues arising out of FIFRA legal mandates. Thus, this proposal will be submitted to OMB for review, and any comments or changes made in response to OMB suggestions or recommendations, are documented in the public record.

B. Regulatory Flexibility Act

This proposed rule was reviewed under the provisions of section 3(a) Regulatory Flexibility Act (RFA) [5 U.S.C. 605(b)]. The RFA requires that agencies take special note of the impact of proposed regulations on small entities. Analysis requirements under the RFA can and should be combined with the analysis required under Executive Order 12866.

The regulatory flexibility analysis of this proposed regulation for plant-pesticides on small entities is demonstrated within the structuring of the four regulatory options proposed. These options were considered after extensive evaluations of the benefit/risk tradeoffs between option cost and risk reduction provided. The Agency has structured the resulting options from a narrow regulatory scope (RIA Option 1) to a broad regulatory scope (RIA Option 4) and, as such, has conducted an "inherent" sensitivity analysis for small firms likely to be affected by this proposed regulation. The Agency has determined that the tradeoffs between the benefits and risks of the proposed regulation are optimized under RIA Option 2, EPA's proposed scope.

C. Paperwork Reduction Act Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request document has been prepared by EPA (ICR No. 1693.01) and a copy may be obtained from Sandy Farmer, Information Policy Branch, (Mail Code 2136), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, or by calling (202) 260–2740.

This collection of information has an estimated reporting burden averaging 1,143 hours per response and an estimated annual recordkeeping burden averaging 74 hours per respondent. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch, (Mail Code 2136), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects in Parts 152 and 174

Environmental protection, Biotechnology pesticides, Pesticides and pests, Plants, Plant-pesticides, Reporting and recordkeeping requirements.

Dated: November 15, 1994.

Carol M. Browner,

Administrator.

Therefore, it is proposed that 40 CFR Chapter I be amended as follows:

PART 152—[AMENDED]

1. In part 152:

a. The authority citation for part 152 would continue to read as follows:

Authority: 7 U.S.C. 136–136y; subpart U is also issued under 31 U.S.C. 9701.

b. In § 152.1, by designating existing text as introductory text and adding paragraphs (a) and (b) to read as follows:

§ 152.1 Scope.

* * * * *

(a) For procedures, requirements and criteria applicable to plant-pesticides, refer to part 174 of this chapter.

(b) [Reserved]

c. In § 152.3, by removing all alphabetic paragraph designations and alphabetically inserting the following definitions to read as follows:

§ 152.3 Definitions.

* * * * *

Genetic material necessary for the production means:

(1) Genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance.

(2) Regulatory regions.

It does not include noncoding, nonexpressed nucleotide sequences.

* * * * *

Living plant means a plant that is alive, including periods of dormancy, and all viable plant parts/organs involved in the plant's life cycle.

* * * * *

Noncoding, nonexpressed nucleotide sequences means the nucleotide sequences are not transcribed and are

not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

* * * * *

Plant-pesticide means a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

Regulatory region means genetic material that controls the expression of the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include promoters, enhancers, and terminators.

* * * * *

d. In § 152.20, by revising paragraph (a)(1) and adding paragraph (a)(4) to read as follows:

§ 152.20 Exemptions for pesticides regulated by another Federal agency.

* * * * *

(a) * * *

(1) Except as provided by paragraphs (a)(3) and (a)(4) of this section, all biological control agents are exempt from FIFRA requirements.

* * * * *

(4) All plants intended for use as biological control agents and any portion thereof, except plant-pesticides, are exempt from the requirements of FIFRA. Plant-pesticides are addressed in part 174, subpart A, of this chapter.

* * * * *

2. By adding part 174 to read as follows:

PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT-PESTICIDES

Subpart A—General Provisions

Sec.

Subpart B—[Reserved]

Authority: 7 U.S.C. 136–136y and 21 U.S.C. 346a and 371.

Subpart A—General Provisions

§ 174.1 Scope and purpose.

Pesticidal substances produced in plants are pesticides as defined in FIFRA section 2. The characteristics of these pesticides such as their production and use in plants, their biological properties, and their ability to spread and increase in quantity in the environment distinguishes them from traditional, chemical pesticides. Therefore, plant-pesticides are subject to different regulatory requirements and procedures than traditional, chemical pesticides. This part 174 sets forth regulatory requirements, criteria, and procedures applicable to plant-pesticides under FIFRA and FFDCA. Unless otherwise provided by this part, the regulations in parts 152 through 173 and parts 177 through 186 of this chapter, where applicable, apply to plant-pesticides. EPA recognizes the unique nature of plant-pesticides necessitates flexibility in the application of regulations designed for traditional pesticides to plant-pesticides.

§ 174.3 Definitions.

Terms used in this part have the same meaning as in FIFRA. In addition, the following terms have the meaning set forth in this section.

Active ingredient, when referring to plant-pesticides only, means a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

Administrator means the Administrator of the United States Environmental Protection Agency or his/her delegate.

Biological control agent means any living organism applied to or introduced into the environment that is intended to function as a pesticide against another organism declared to be a pest by the Administrator.

Bridging crosses between plants means the utilization of an intermediate plant in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote.

EPA means the United States Environmental Protection Agency unless otherwise specified.

FFDCA means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*)

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136–136y).

Genetic material necessary for the production means:

(1) Genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance.

(2) Regulatory regions.

It does not include noncoding, nonexpressed nucleotide sequences.

Genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance does not include regulatory regions or noncoding, nonexpressed nucleotide sequences.

Inert ingredient, when referring to plant-pesticides only, means any substance, such as a selectable marker, other than the active ingredient, and the genetic material necessary for the production of the substance, that is intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient.

Living plant means a plant that is alive, including periods of dormancy, and all viable plant parts/organs involved in the plant's life cycle.

Noncoding, nonexpressed nucleotide sequences means the nucleotide sequences are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, other than any article that:

(1) Is a new animal drug under FFDCA section 201 (w); or

(2) Is an animal drug that has been determined by regulation of the Secretary of Health and Human Services not to be a new animal drug; or

(3) Is an animal feed under FFDCA section 201(x) that bears or contains any substances described by § 152.3(s)(1) or (2) of this chapter.

Plant-pesticide means a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

Recipient plant means the plant into which the plant-pesticide is introduced and in which the plant-pesticide is produced.

Regulatory region means genetic material that controls the expression of the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include promoters, enhancers, and terminators.

Sexually compatible, when referring to plants, means capable of forming a viable zygote through the fusion of two

gametes, including the use of bridging crosses or wide crosses between plants.

Source means the donor of the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance.

Wide crosses between plants means to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre- and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures or any other technique that the Administrator determines meets this definition.

§ 174.5 Scope of coverage.

(a) Plant-pesticides not exempt from the requirements of FIFRA under paragraph (b) of this section are subject to the requirements of FIFRA.

(b) All plant-pesticides (both the pesticidal substance and the genetic material necessary for its production) meeting at least one of the following criteria are exempt from the requirements of FIFRA:

(1) The genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from plants that are sexually compatible with the recipient plant and has never been derived from a source that is not sexually compatible with the recipient plant.

(2) The pesticidal substance acts primarily by affecting the plant so that the target pest is inhibited from attaching to the plant, penetrating the plant, or invading the plant's tissue in at least one of the following ways:

(i) The pesticidal substance acts as a structural barrier to attachment of the pest to the host plant, a structural barrier to penetration of the pest into the host plant, or a structural barrier to spread of the pest in the host plant, for example, through the production of wax or lignin, or length of trichomes (plant hairs).

(ii) The pesticidal substance acts in the host plant to inactivate or resist toxins or other disease-causing substances produced by the target pest.

(iii) The pesticidal substance acts by creating a deficiency of a plant nutrient or chemical component essential for pest growth on/in the host plant.

(3) The pesticidal substance is a coat protein from a plant virus.

§ 174.7 Submission of information regarding potential unreasonable adverse effects.

Any person who sells or distributes any plant-pesticide exempt under § 174.5 who obtains any information regarding potential unreasonable adverse effects on human health or the environment must within 30 days of receipt of such information submit the information to EPA, unless the person has actual knowledge that EPA has been adequately informed of such information.

§ 174.9 Confidential business information claims for plant-pesticide submissions.

Although it is strongly recommended that the submitter minimize the amount of data and other information claimed as CBI, a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a submission for a plant-pesticide. (See part 2, subpart B, of this chapter.) To assert such a claim, the submitter must comply with the following procedures:

(a) Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time will be considered a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of FIFRA, with no further notice to the submitter.

(b) Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter should refer to § 2.205(e)(4) of this chapter for points to address in the substantiation. If such comments are marked confidential when submitted to EPA, they will be treated as such in accordance with § 2.205(c) of this chapter. EPA will consider incomplete all plant-pesticide submissions containing information claimed as CBI that are not accompanied by substantiation, and will suspend the review period of such submissions until the required substantiation is provided.

Subpart B—[Reserved]

[FR Doc. 94–28822 Filed 11–22–94; 8:45 am]
BILLING CODE 6560–50–F

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40 CFR Part 180

[OPP–300368; FRL–4758–8]

RIN 2070–AC02

Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes an exemption from the requirement of a tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA) for specific categories of pesticidal substances produced by plants to protect them against pests and disease. Pesticidal substances produced by plants, along with the genetic material necessary for the production of these substances, have been designated "plant-pesticides" by the Agency. The categories of plant-pesticides EPA is proposing to exempt from the requirement of a tolerance are based upon evaluation of the potential for new dietary exposures to these pesticidal substances when they are produced in plants or plant parts used as raw agricultural commodities. EPA believes that a tolerance for these categories of plant-pesticides is not necessary to protect the public health.

DATES: Comments identified by the docket control number [OPP–300368] must be received on or before January 23, 1995.

ADDRESSES: Submit written comments by mail to: Program Resources Section, Public Response and Program Resources Branch, Field Operations Division (7506C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the Virginia address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Bernice Slutsky, Science and Policy Staff, Office of Prevention, Pesticides and Toxic Substances (7101), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone number: 202–260–6900.

SUPPLEMENTARY INFORMATION:

I. Introduction

Substances that are produced in plants to enable the plants to resist pests or disease are pesticides under section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (i.e., if they are . . ."intended for preventing, destroying, repelling, or mitigating any pest") regardless of whether the pesticidal capabilities evolved in the plants or were introduced by breeding or through the techniques of modern biotechnology. These substances, along with the genetic material necessary to produce the substances, are designated by the Agency as "plant-pesticides."

There are a number of types of substances that are produced in plants to protect them against pest attack and disease. For example, phytoalexins (plant-produced substances that act against microbial phytopathogens) could be considered plant-pesticides because of their role in plant resistance to plant pests. These substances are examples of plant-pesticides that can be introduced into a plant through traditional breeding. Another example of a plant-pesticide is an insecticidal delta endotoxin from the bacterium, *Bacillus thuringiensis*, introduced into plants through biotechnology techniques to impart or enhance resistance to insect pests.

In the past, EPA has addressed, under FFDCA, how it regulates substances that are extracted from plants and used as pesticides on food or feed. For example, a tolerance has been set for pyrethrum that is extracted from plants and applied to food or feed. However, until now, the Agency has not clearly explained how it intends to regulate pesticidal substances produced in plants and not extracted from the plant ("plant-pesticides") under FFDCA. For example, if a food plant could be modified, for pesticidal purposes, to produce pyrethrum, EPA has not explained how this pyrethrum would be regulated under FFDCA.

The Agency is proposing to exempt certain categories of plant-pesticides that the Agency believes would not result in new dietary exposures (e.g., not significantly different from what humans are currently exposed to in the food supply) and therefore do not require the establishment of a tolerance to protect the public health. There are circumstances where EPA believes that plant-pesticides should be regulated by EPA for the purpose of either setting a tolerance or issuing a specific exemption from the requirement of a tolerance for a particular plant-pesticide. In general, plant-pesticides that would result in significantly new or different dietary exposures would be subject to EPA review under FFDCA tolerance procedures. These categories of plant-pesticides would not be exempt from the requirement of a tolerance under this proposal.

This proposed rule, is one of several documents published in today's **Federal Register** that address EPA's regulation of plant-pesticides. The other notices are: (1) A proposed policy statement that generally describes how EPA proposes to regulate plant-pesticides under the FIFRA and FFDCA ("Plant-pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act; Proposed Policy"); (2) a proposed regulatory amendment that would describe categories of plant-pesticides that are subject to or exempt from regulation under FIFRA and clarifies the status of plants that produce plant-pesticides ("Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule"); (3) a proposed exemption from the requirement of a tolerance under FFDCA for viral coat proteins ("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants"); and (4) a proposed exemption from the requirement of a tolerance under FFDCA for nucleic acids, including deoxyribonucleic and ribonucleic acids ("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants"). A plant-pesticide would be defined as a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant. The definition of the active ingredient for plant-pesticide would be the same as the definition for plant-pesticide (see **Federal Register** document entitled, "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule").

This proposal addresses only the component of plant-pesticides comprising the *pesticidal substance* produced in food plants. The component comprising the genetic material necessary for the production of these substances is addressed in another proposed exemption from the requirement of a tolerance for nucleic acids produced in plants as part of a plant-pesticide (see the **Federal Register** document entitled, "Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants").

II. Statutory Authority

This exemption from the requirement of tolerance is being proposed under the authority of section 408(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et. seq.). The reorganization plan of 1970 reallocated the authority under FFDCA to regulate pesticide residues in foods and animal feeds to EPA. Under FFDCA section 408, pesticide chemicals added to a raw agricultural commodity, that are not "generally recognized as safe" (GRAS), are deemed to be unsafe unless a tolerance, or an exemption from the requirement of a tolerance, for such pesticide residues is established and the pesticide residue is within the tolerance limits. Section 408 of the FFDCA applies to all "pesticide chemicals" which are defined in section 201(q) of the FFDCA as:

> any substance which, alone, in chemical combination or in formulation with one or more other substance, is "a pesticide" within the meaning of [FIFRA] . . .and which is used in the production, storage, or transportation of raw agricultural commodities.

Under FFDCA section 408(c), EPA can exempt, by regulation, any pesticidal chemical from the necessity of a tolerance when such tolerance is not necessary to protect the public health. The result of such an exemption is also to authorize residues of the pesticidal chemical in any processed foods made from the raw agricultural commodity that contain the residue as a result of the pesticide on the raw agricultural commodity.

III. Proposed Exemptions

In developing this proposal, EPA identified three categories of plant-pesticides that can be produced in recipient food plants where the recipient food plant would be defined as the plant into which the plant-pesticide is introduced and in which the plant-pesticide is produced. The three categories of plant-pesticides are: (1) Plant-pesticides that are derived from food or non-food plants that are closely related to the recipient plant; (2) plant-pesticides that are derived from food plants that are not closely related to the recipient food plant and that would not result in significantly different dietary exposures when produced in the recipient food plant; and (3) plant-pesticides either derived from nonfood plants that are not closely related to the recipient plant or derived from a nonplant source. EPA is proposing to exempt from the requirement of a tolerance plant-pesticides in categories (1) and (2) above and these are defined

in the proposed regulatory text. In the preamble of this document, these two categories are described in Units III.A. and III.B., respectively and analyzed in Unit III.D. Plant-pesticides in category (3) above would not be exempt from the requirement of a tolerance under this proposal.

A. Category 1: Exemption of Plant-pesticides Derived from Closely Related Plants

This exemption is based upon the premise that new dietary exposures would not likely arise for plant-pesticides produced in recipient food plants if the genetic material leading to the production of the pesticidal substance is derived from closely related plants.

For the purposes of describing this category of plant-pesticides, EPA is presenting three options for a standard based on the relatedness of plants. These options are described in Unit III.A. with the analysis of the options in Unit III.D. of this preamble. The Agency's aim when it selects one of these approaches for its final rule is to: (1) Distinguish, on a risk basis, those plant-pesticides that would result in new dietary exposures from those that would not; (2) provide a standard of sufficient regulatory clarity so that the public, industry, and the Agency can easily identify those plant-pesticides that would be subject to regulation; and (3) create as similar a scope of regulation as possible under FFDCA and FIFRA given the differences in mandate and structure of the two statutes. (See "Plant-pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule" for details on the scope options proposed under FIFRA.) Note, that some options offered in the proposed rule under FIFRA are not offered in this proposed regulation under FFDCA because EPA believes that they would not be appropriate for describing a category of plant-pesticides that would not present new dietary exposures. The options that are not discussed under FFDCA are not EPA's preferred option under FIFRA.

1. *Option 1: Plant-pesticides derived from sexually compatible plants.* The preferred approach EPA is proposing to use, in establishing this exemption, is based on the concept of sexual compatibility as a measure of relatedness between plants. The use of the standard of sexual compatibility is embodied in the following language from the proposed regulatory text:

Residues of pesticidal substances produced in living plants as plant-pesticides are exempt from the requirement of a tolerance if the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from plants that are sexually compatible with the recipient plant and has never been derived from a source that is not sexually compatible with the recipient plant;. . . .

2. *Option 2: Plant-pesticides derived from plants within the same genus or from sexually compatible plants.* The standard under this option would rely primarily on the taxonomic grouping of genus and would exempt from the requirement of a tolerance plant-pesticides that are moved between source and recipient plants that are in the same genus. The assumption underlying this approach is that this grouping correlates to a relatively high degree of relatedness even though not all plants in a genus are sexually compatible. For example, traits ranging from flower morphology to the presence of particular alkaloids and flavonoids have been used to determine whether to classify a plant species in a particular genus. Recognizing that some plants that are sexually compatible are classified in different genera and assuming that sexual compatibility correlates with a high degree of relatedness, EPA also includes a provision extending the exemption to include sexually compatible plants from any genera. The language defining this option would be as follows. [Residues of pesticidal substances produced in living plants as plant-pesticides are exempt from the requirement of a tolerance if:]

The genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance:

(1) Is derived from plants that are within the same genus as the recipient plant [regardless of sexual compatibility] or, is derived from plants that are sexually compatible with the recipient plant; and

(2) Has never been derived from a source outside the same genus that is not sexually compatible with the recipient plant.

B. Category 2: Plant-pesticides Derived from Food Plants that are Not Closely Related to the Recipient Plant

There are circumstances where experience with exposure can be inferred for plant-pesticides introduced into food plants from other food plants that are not closely related to the recipient plant. For plant-pesticides derived from a *food plant* that is not closely related to the recipient food plant, there is experience with exposure because both plants have contributed to the food supply. Thus, the Agency is proposing to exempt from the requirement of a tolerance plant-pesticides derived from food plants that are not closely related to the recipient plant, if there would not be significantly different dietary exposures when the plant-pesticide is produced in the recipient food plant. The criteria defining this exemption are as follows:

Residues of pesticidal substances produced in living plants as plant-pesticides are exempt from the requirement of a tolerance when the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from plants that are not sexually compatible with the recipient plant if:

(1) The genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from food plants; and

(2) The pesticidal substance would not result in significantly different dietary exposures.

C. Terms Used

The following are terms used in the two options for the Category 1 exemption presented in Unit III.A. and the Category 2 exemption presented in Unit III.B. of this preamble.

The phrase "the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance" refers to genetic material that directly encodes for the production of a pesticidal substance or encodes for enzymes that lead to the production of a pesticidal substance (e.g., phenylalanine ammonia-lyase (PAL) catalyzes the first reaction in the synthesis of such phytoalexins as pterocarpans in *Leguminosae* and furanocoumarins in *Solanaceae* and *Umbelliferae*; Ref. 2). For the purposes of this exemption under FFDCA, this phrase is *not* intended to include regulatory regions or noncoding, nonexpressed nucleotide sequences when the gene would otherwise be exempt. For the exemptions proposed in this document, these regulatory regions and noncoding, nonexpressed nucleotide sequences *may be derived from any source.* For example, if a viral promoter attached to a corn gene encoding a pesticidal substance is introduced into another corn variety, the gene and the viral promotor genetic construct would meet the criteria of these exemptions.

The definition for "sexually compatible" would mean being capable of forming a viable zygote through the fusion of two gametes and can include the use of bridging crosses and the use of wide cross breeding techniques of surgical alteration of the plant pistol, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre- and post- pollination hormone treatments, manipulation of chromosome numbers, and embryo culture. Wide crosses, for the purpose of this exemption, also include ovary and

ovule cultures. EPA believes that the production of viable zygotes through these techniques indicates a sufficient level of relatedness between the parental plants involved to be included under the rubric of "sexually compatible."

The phrase, ". . .result in significantly different dietary exposure. . ." relates only to the Category 2 exemption and would mean:

(1) The pesticidal substance is produced in inedible portions of the source food plant, but, in the recipient plant, the pesticidal substance is present in the plant's edible portions;

(2) The pesticidal substance is produced in the immature, but not in the mature, edible portions of the source food plant, but, in the recipient plant, the pesticidal substance is present in the mature, edible portions;

(3) The pesticidal substance is from a source food plant normally cooked or processed prior to consumption and is produced in a recipient plant that is not normally cooked or processed prior to consumption;

(4) The pesticidal substance is derived from a source food plant that is not a major crop for dietary consumption and is introduced into a recipient plant that is a major crop for dietary consumption.

The "source food plant" is the donor of the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance.

The phrase ". . .has never been derived from a source plant that is not sexually compatible to the recipient plant. . ." (Category 1) is meant to indicate in the proposed regulatory text that the plant-pesticide would not qualify for the exemption in this proposal if the genetic material, for example, is introduced into a plant from a sexually incompatible source and subsequently introduced into other, sexually compatible plants. An example of such a situation would be if the *Bacillus thuringiensis* delta endotoxin is introduced into wheat and the endotoxin producing wheat plants subsequently hybridized using wide cross techniques with rye to produce triticale. The endotoxin produced in the triticale would not be eligible for the exemption.

D. Analysis of Exemptions

This unit contains analysis of the two options presented in Unit III.A., the exemption presented in Unit III.B., and the relationship between the options in Unit III.A. and the exemption in Unit III.B. of this preamble.

1. *Analysis of options for category 1 exemption presented in Unit III.A.* Under FFDCA, the options must be examined specifically within the context of the food supply and dietary consumption. Many substances having pesticidal activity occur naturally at low concentrations in the edible parts of plants and have long been accepted as part of the human diet. Extensive use and experience show the safety of foods containing these substances. For many foods, the naturally occurring toxicants they may contain, including pesticidal substances, are known (Ref. 1). Also, the established practices that plant breeders employ in selecting and developing new plant varieties, such as chemical analyses, taste-testing, and visual analyses, have historically proven to be reliable for ensuring food safety. That there are few examples of new plant varieties causing food safety concerns, despite the large numbers of new varieties introduced into commerce each year, is a reflection of the effectiveness of this process.

Sexually compatible plants are more apt to share traits than are unrelated plants. It is a common expectation that similarity is associated with the degree of relatedness. Natural hybridization and selection have produced groups of plants which have a common gene pool. Generations of artificial hybridization practiced to produce improved crops for cultivation have tended to increase the extent of relatedness among elements of a broader segment of agricultural plants.

The practice of saving seed from desirable plants has been going on for thousands of years, and using controlled crosses to produce plant hybrids has been documented since the eighteenth century. Since the rediscovery of Mendel's work on the inheritance of traits, there is a base of experience of 50 to 100 years of breeding for most major crops. During that time, it has been common agricultural practice to cross sexually compatible wild relatives with crop plants to develop crop varieties with better pest resistance. Sexually compatible crop varieties are also crossed with each other to achieve better pest resistance in their progeny.

EPA believes, based on this experience, that most plant varieties developed by plant breeders using genetic material from plants that meet the sexually compatible standard produce food that is safe for human consumption and/or that appropriate processing procedures are widely known and routinely used by consumers in preparation of food from such sources.

A plant-pesticide would meet the criteria of this standard if the plants that are used as genetic donors are not themselves food plants, as long as they are sexually compatible with the recipient food plant that is producing the plant-pesticide. It has been common agricultural practice to introduce traits from sexually compatible wild relatives into plant varieties to be used as food plants. These wild, sexually compatible relatives of cultivated plants do not have any history of human consumption but have safely contributed traits through sexual recombination to cultivars on the market. Food plant varieties developed in this way have been introduced and consumed by humans for many years with no observed adverse affects. For example, under this standard, a wild species related to tomato may be used as a source of genetic material in developing a cultivated tomato variety.

EPA proposes to extend the concept of sexual compatibility to include wide crosses because wide crosses are commonly used to expand the gene pool for varietal improvement, and EPA believes that the use of wide crosses to produce a viable zygote indicates a fairly high degree of relatedness and thus a high probability that the parental plants have common constitutions. However, for regulatory purposes it is somewhat difficult to define what constitutes a wide cross since techniques may change over time. EPA is thus proposing to define, for the purposes of this rulemaking, wide crosses based on existing techniques, with a provision to add to the definition as the Administrator determines is appropriate.

As described in Unit III.A. of this preamble, EPA is considering a second option for describing relatedness based primarily on the taxonomic standard of genus rather than on sexual compatibility alone. Under this approach, a plant-pesticide would be exempt if the genetic material encoding for a pesticidal substance or leading to the production of a pesticidal substance is derived from a plant within the same genus as the recipient plant. EPA recognizes that some plants that are closely related (as evidenced by sexual compatibility) are not classified in the same genus. Under this second option, EPA would extend the exemption to plant-pesticides derived from plants sexually compatible with the recipient plant, as well as to intrageneric plant-pesticides.

Plant species within the same genus may have become separated by geography, timing of pollination, or other factors to form two distinct populations no longer sexually compatible. Events such as mutation and environmental selection most likely occurred and reinforced the isolation and uniqueness of the gene pools. However, the ability to overcome these incompatibility barriers between species

in the same genera through human intervention (e.g., wide crosses) is evidence that such plants are fairly closely related and share a common constitution. The majority of successful wide crosses and bridging crosses to date have occurred between species within the same genus.

However, taxonomy of plant genera may be an artificial standard within the context of the food supply since there may be species within any given genus that are not used as food or may not have contributed traits to food through breeding and thus experience with their risks may not exist. In addition, the experience base (e.g., experience with whether or not naturally occurring toxicants are present) for most of the species within most genera is more limited than for those species comprising the major food crops.

Under Option 1, a plant-pesticide produced from genetic material derived from a plant in the same genus as, but not sexually compatible with, the recipient plant would not qualify for the exemption. In contrast, under Option 2, this plant-pesticide would qualify for the exemption. It is, therefore, possible under Option 2 for a plant-pesticide to be exempt from the requirement of a tolerance without the base of experience that breeders have for sexually compatible plants.

Finally, none of the options are intended to exempt plant-pesticides which are significantly different in structure or function from the plant-pesticide as it occurs in the source plant. Such significantly modified plant-pesticides would no longer be considered by the Agency to be "derived from the source plant." Rearrangements or modifications of the sequence encoding a plant-pesticide, for example, could result in plant-pesticides with significantly different structures and/or functions from that in the source plant and these would not be exempt. If this type of modification were to occur, the base of experience for that plant-pesticide in food would no longer be relevant.

2. *Analysis of Category 2 exemption presented in Unit III.B.* Based on the experience with food plants, conclusions as to dietary safety of these foods can be drawn. EPA has concluded that an exemption from the requirement of a tolerance is appropriate for certain pesticidal substances produced from genetic material derived from food plants that are not close relatives to the recipient plant producing the plant-pesticide if there will not be significantly different human dietary exposures. The Agency has defined a set of criteria to determine whether significantly different dietary exposures from the these plant-pesticides would occur. For example, if a pesticidal substance is normally only produced in inedible portions or immature fruit of the food plant, the Agency would require a tolerance review if the modified food plant were to produce that substance in its mature fruit or edible portions. For example, tomatine is a toxicant produced in much higher amounts in immature tomato fruit (that is normally not eaten) than it is in the mature fruit. If the genetic material leading to the production of tomatine were introduced into a plant for pesticidal purposes such that the tomatine were produced in the mature fruit as it is in the immature fruit, EPA would need to conduct a tolerance review to determine whether a tolerance is necessary to protect the public health. Similarly, if a pesticidal substance is produced in a food that is almost always cooked or processed prior to consumption, the Agency would want to conduct a tolerance review if another food plant that is not cooked or processed prior to consumption is modified to produce the substance. For example, some beans are rich in lectins, glycoproteins that are natural toxicants. Soaking and cooking the beans destroys the lectin. If the genetic material encoding for the lectin were transferred, for pesticidal purposes, from beans to a plant which is not normally cooked (e.g., lettuce), EPA would need to conduct a tolerance review. A significantly different dietary exposure could also result if a widely consumed food staple such as corn is modified to produce a pesticidal substance from a food crop with minor consumption such as eggplant.

EPA is also considering adding another criterion to the exemption from the requirement of a tolerance for categories of plant-pesticides that would not result in significantly different dietary exposures (see Unit III.B. of this preamble). This criterion would address the potential for allergenicity of plant-pesticides in food. Under this criterion, if a plant-pesticide is derived from a commonly allergenic food, the plant-pesticide would not be exempt from tolerance requirements and the Agency would conduct a tolerance review on a case-by-case basis to determine whether to establish an exemption from the requirement of a tolerance, establish a tolerance, or deny a tolerance. Some examples of foods that commonly cause an allergenic response are milk, eggs, fish, crustacea, molluscs, tree nuts, wheat, and legumes (particularly peanuts and soybeans).

3. *Analysis of the relationship between the options for the Category 1 exemption in Unit III.A and the Category 2 exemption in Unit III.B.* Option 2 discussed in Unit III.A. of this preamble has different implications for the exemption described in Unit III.B. of this preamble than does Option 1 in Unit III.A. If the concept in the Unit III.B. exemption were transcribed to fit with Option 2, a distinction would be drawn between plant-pesticides derived from food plants in the same genus as the recipient plant but not sexually compatible with the recipient plant, and plant-pesticides derived from food plants outside the same genus as the recipient plants and also not sexually compatible with the recipient plant. This distinction may be somewhat artificial under FFDCA since it is based on a taxonomic standard rather than one of experience with dietary exposure. The Unit III.B. exemption would read as follows if it were coupled with Option 2:

> Residues of pesticidal substances produced in plants that are *not in the same genus* as the recipient plants are exempt from the requirement of a tolerance if:
>
> (1) the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from food plants and
>
> (2) the pesticidal substances would not result in significantly different dietary exposures.
>
> "Significantly different dietary exposures" would be defined as in Unit III.C. of this preamble.

Modifying the exemption in Unit III.B. in such a way raises the following specific question. Should EPA treat plant-pesticides derived from sexually incompatible food plants *outside* the genus of the recipient plant differently from plant-pesticides derived from sexually incompatible food plants *within* that genus? In the first case, the plant-pesticide (produced from genetic material derived from sexually incompatible food plants outside the genus of the recipient plant) would have to meet certain criteria to qualify for an exemption. In the latter case, the plant-pesticide (produced from genetic material derived from sexually incompatible food plants within the genus of the recipient plant) would be exempt unconditionally from the requirement of a tolerance (i.e., without any conditional criteria describing "significantly different dietary exposure"). The base of experience in relation to food safety may not justify *not* applying these criteria to sexually incompatible food plants within the same genus as the recipient plant. In addition, greater confusion concerning

the status of a particular plant-pesticide may arise under the Option 2/ transcribed Unit III.B. exemption than with the Option 1/Unit III.B. exemption.

IV. External Review

In developing its approach to plant-pesticides under FFDCA, EPA requested the advice of two scientific advisory committees on FFDCA related issues. On July 13, 1993, EPA requested the advice of a Subcommittee of the EPA Biotechnology Science Advisory Committee (BSAC) on a series of scientific questions dealing with EPA's approach under the FFDCA. On January 21, 1994, a joint meeting of a Subpanel of the FIFRA Scientific Advisory Panel (SAP) and BSAC was held and EPA asked advice from this joint Subpanel on EPA's approach under FFDCA. The primary goal of the questions posed at both meetings was to identify, for regulatory purposes, those circumstances in which new or significantly different human dietary exposures to plant-pesticides could occur. The reports from these meetings are available in the public docket for this proposed rule.

At the July 13, 1993, meeting the Agency questioned the subcommittee on: what information exists on which plant-pesticides in food might be of concern should their levels be significantly increased via breeding or via engineering methodologies; whether information exists on exposure in the diet to levels of plant-pesticides in raw agricultural commodities; and how plant breeders ensure that natural plant toxicants do not exceed acceptable levels in foods.

The Subcommittee said:

"Breeders depend primarily on familiarity with food crops (e.g., knowledge of which crop plants have the ability to produce which toxicants) to ensure the safety of food from the various crop plant varieties. If the plant species is known to possess the ability to produce a toxicant (e.g., potato plants can express solanine), new varieties of the plant are tested for toxicant content (e.g., potato varieties are tested for alkaloid content). At this time, most of this knowledge is part of breeders' experience; no formal, complete data bases exist."

However, the Subcommittee believed that in light of breeders' experience and familiarity with the characteristics of crop plants and their sexually compatible relatives, the screening procedures employed in traditional breeding and known food processing considerations, plant-pesticides under certain conditions could be exempted from regulatory oversight. The Subcommittee suggested the following scheme to identify those groupings wherein plant-pesticides might present new and novel exposures. They suggested that:

(1) Plant pesticides in plants commonly consumed by humans as food be exempt as long as the plant's genetic material is derived from related plants within the same family that have contributed traits to the food plant through the mechanism of sexual recombination (including wide crosses and embryo rescue).

(2) Plant pesticides in plants in which the genetic material is derived from plants commonly used as food, but which are not members of the same family would be subject to review if one or more of the following criteria are met:

(a) The pesticidal substance, normally produced in the inedible portions of the source food plant, is present in the edible portions of the modified host plant.

(b) The pesticidal substance, derived from a source food plant almost always cooked or processed, is introduced into a food plant that is not cooked or processed prior to consumption.

(c) The pesticidal substance is derived from a minor food crop and introduced into a major food crop.

(3) Any pesticidal substance intentionally modified to have a significantly different structure, function or composition from that known to exist in food would require a food tolerance determination by the Agency.

(4) Any pesticidal substance introduced into a food plant and derived from a source not used as food, except as described in (1) above, would require review under FFDCA.

At the January 21, 1994, joint SAP/ BSAC Subpanel meeting, the use of sexual compatibility (and thus sexual recombination) and/or taxonomy as a standard for the potential for significantly different dietary exposures was once again discussed. In response to the question of whether plants in a sexually compatible population are likely to share many substances or traits, the joint Subpanel agreed that sexually compatible plants are more likely to have a common constitution than unrelated plants and thus are less likely to lead to novel exposures. They noted that natural hybridization and selection have produced groups of plants which have a common gene pool. Generations of artificial hybridization to produce improved cultivated plants have tended to increase the extent of relatedness among elements of a broader segment of the natural diversity. In addition, modern techniques of genetic mapping have revealed the presence of genetic loci in cultivated plants that previously were considered to be present only in the wild species.

In regard to the correlation of the concept of "genus" with significantly different exposures, the joint Subpanel noted that the taxonomic classification of a genus and the measure of sexual compatibility are closely interrelated. Sexual compatibility tends to promote genetic interchange, and this interchange leads to populations of plants more like each other than like groups that have been sexually isolated. Because plants in the same genus likely have common ancestors that at some period in their evolution were sexually compatible, plants in the same genus are more apt to be sexually compatible with each other than with plants from other genera. Some barriers to sexual compatibility exist between species in the same genus even though the species are similar taxonomically. However, many of these sexual barriers can be overcome through the use of wide cross techniques by breeders.

The Agency also included a question, at the January 21, 1994, joint BSAC/SAP meeting, concerning an approach using a criterion based on the process used to modify the plant, e.g., recombinant DNA methodologies. As described in the report of the joint BSAC/SAP Subpanel meeting, if the Agency were to use this approach, it would first exempt plant-pesticides developed through techniques other than those of modern biotechnology from its regulatory scope. For those plant-pesticides that are not exempted because they were developed through techniques of modern biotechnology, the exemptions proposed by the Agency would apply (i.e., Category 1 and 2 exemptions; see Units III.A. and III.B. of this preamble)

EPA's response: EPA has utilized the suggestions of the BSAC Subcommittee and joint SAP/BSAC Subpanel in developing this proposal. In particular, EPA has utilized the concepts put forth by the advisory committees in developing the language of the Agency's preferred approaches. EPA also used the advice in developing the alternative options.

EPA captured in Option 1 in Unit III.A. of this preamble the concept of exempting from tolerance requirements plant-pesticides derived from plants sexually compatible with the recipient plants as suggested by the first part of a two part recommendation of the BSAC subcommittee at the July 13, 1993, meeting; the BSAC subcommittee suggested exemption of plant-pesticides from "related plants within the same family that have contributed traits to the food plant through the mechanism of sexual recombination (including wide crosses and embryo rescue)." This approach was reaffirmed at the January 21, 1994, joint SAP/BSAC meeting.

The Agency, in creating the approach described in Unit III.B. of this preamble, essentially captured the second half of the scheme suggested by the BSAC

subcommittee at the July 13, 1993, meeting; i.e., that under certain conditions plant-pesticides encoded by genetic material from food plants that are not sexually compatible can be exempt.

In terms of the alternative option, at the January 1994 meeting, the concept of "genus" as a criterion of relatedness between plants was confirmed, and EPA used that concept to create Option 2 of Unit III.A. of this preamble.

With regard to the advice of the January 21, 1994, joint SAP/BSAC Subpanel concerning the use of a process-based criterion in the scope, if the Agency were to use this approach, plant-pesticides developed through techniques other than those involving *in vitro* manipulation of genetic material would be exempt. In order to meet the recommendations of the joint Subpanel, the Agency would define this category of plant-pesticides in the following way: The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is extracted from an organism and introduced into the genome of the recipient plant or is synthesized *in vitro* and introduced into the genome of the recipient plant. The exemptions proposed by the Agency in Unit III. of this preamble would be used in concert with this criterion. The Agency believes this approach would meet the recommendations of the SAP/BSAC joint Subpanel. The Agency is soliciting comment on this approach (see Unit V. of this preamble).

V. Request for Comment

The Agency requests comments on whether EPA has appropriately identified in this proposed exemption from the requirement of a tolerance those plant-pesticides that are not likely to result in new dietary exposures. EPA proposes to exempt from the requirement of a tolerance under FFDCA: (1) Plant-pesticides derived from closely related plants and (2) under certain conditions, plant-pesticides derived from food plants that are not sexually compatible with the recipient food plant because EPA believes tolerances for these plant-pesticides are not necessary to protect the public health.

Under the first exemption (Category 1), EPA has described two options, with Option 1 presented in the proposed regulatory text. EPA requests comments on these three options, specifically as to whether they appropriately identify, plant-pesticides that would not result in new dietary exposures and whether the language it uses in the two options to define this grouping for regulatory purposes is clear. EPA also requests comments on which option is most appropriate and why.

With regard to an exemption criterion based on the process used to modify the plant, the Agency is soliciting comment on the joint BSAC/SAP Subpanel advice and the utility of an approach based on that advice (see Unit IV. of this preamble). EPA also requests comment on whether the group of plant-pesticides that would be regulated under this approach would be equivalent to the group of plant-pesticides that would be regulated under Options 1, or 2.

EPA requests comments on whether it has appropriately identified in the second exemption (Category 2) those plant-pesticides that should not be exempted because significantly different dietary exposures could occur from plant-pesticides derived from food plants not closely related to the recipient plant (i.e., substances produced in inedible portions of source plants but in edible portions of recipient plant, in immature fruits of source plant but in mature fruits of recipient plant, derived from plants normally cooked or processed before consumption and introduced into a plant not normally processed or cooked, or derived from a crop that is *not* a major crop for human dietary consumption and introduced into a major crop). EPA requests comment on whether the language it used to describe these criteria is sufficiently clear. It requests comment on whether cereal grains would be an appropriate category to be included in the definition of "major crops for human dietary consumption." EPA also recognizes that some crops are highly consumed by children but not by the rest of the population and requests comment on whether these criteria adequately address categories of crops that are highly consumed by children.

The Agency also specifically requests comment on whether it should include, as a qualification to the second exemption (Category 2) a criterion restricting the possibility that a breeder might take a plant-pesticide derived from a non-food plant and introduce it into a sexually compatible food plant (under the Category 1 exemption described in Unit III.A. of this preamble) and then subsequently move the plant-pesticide into a sexually incompatible food plant (under the Category 2 exemption described in Unit III.B. of this preamble). By bridging these two exemptions, breeders might take a plant-pesticide from a wild relative which is never eaten and introduce it into another crop that is not sexually compatible to the wild relative. The Agency is also requesting comment on whether this would be more critical to Option 1 or Option 2. The Agency is also requesting comment on whether, for the Category 2 exemption, a qualification should be included restricting the possibility that a plant-pesticide from a nonplant source, such as *Bacillus thuringiensis*, is introduced into a food plant and then subsequently introduced into another sexually incompatible food plant.

VI. Rulemaking Record and Procedures

Any person who has registered or submitted an application for registration of a pesticide, under FIFRA as amended, which contains any plant-pesticide that falls within a category proposed for exemption may request within 30 days after publication of this proposed rule in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

EPA has established a record for this rulemaking. Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, (OPP–300368). All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the location listed under the ADDRESSES unit from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

VII. Regulatory Assessment Requirements

The Office of Management and Budget has exempted this proposed rule from the requirement of review pursuant to Executive Order 12866.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

This proposed rule is not subject to the Paperwork Reduction Act because it does not contain any collection of information requirements.

VIII. References

(1) International Food Biotechnology Council, 1990. Biotechnologies and food: Assuring the safety of foods produced by genetic modification. In: Regulatory Toxicology and

Pharmacology. Vol. 12. Academic Press, New York.

(2) Lamb, C.J., J.A. Ryals, E.R. Ward, and R.A. Dixon. 1992. Emerging strategies for enhancing crop resistance to microbial pathogens. Bio/Technology. 10:1436–1445.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Plants, Plant-pesticides.

Dated: November 15, 1994.

Carol M. Browner,

Administrator.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 would continue to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. By adding § 180.1137 to read as follows:

§ 180.1137 Plant-pesticides; exemptions from the requirement of a tolerance.

(a) Residues of pesticidal substances produced in living plants as plant-pesticides are exempt from the requirement of a tolerance if the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from plants that are sexually compatible with the recipient plant and has never been derived from a source that is not sexually compatible with the recipient plant.

(b) Residues of pesticidal substances produced in living plants as plant-pesticides are exempt from the requirement of a tolerance when the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from plants that are not sexually compatible with the recipient plant if:

(1) The genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance is derived from food plants.

(2) The pesticidal substances would not result in significantly different dietary exposures.

(c) For the purposes of this section, the following definitions apply:

Bridging crosses between plants means the utilization of an intermediate plant in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote.

Food plant means a plant which, either in part or *in toto*, is used as food by humans.

Genetic material necessary for the production means:

(1) Genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance.

(2) Regulatory regions.

It does not include noncoding, nonexpressed nucleotide sequences.

Genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance does not include regulatory regions or noncoding, nonexpressed nucleotide sequences.

Living plant means a plant that is alive, including periods of dormancy, and all viable plant parts/organs involved in the plant's life cycle.

Major crops for human dietary consumption means wheat, corn, soybeans, potatoes, oranges, tomatoes, grapes, apples, peanuts, rice, beans, and any other crop that the Agency has determined is a major crop for human dietary consumption.

Noncoding, nonexpressed nucleotide sequences means the nucleotide sequences are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

Plant-pesticide means a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

Recipient plant means the plant into which the plant-pesticide is introduced and in which the plant-pesticide is produced.

Regulatory region means genetic material that controls the expression of the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include promoters, enhancers, and terminators.

Result in significantly different dietary exposure means:

(1) The pesticidal substance is produced in inedible portions of the source food plant, but, in the recipient plant, the pesticidal substance is present in the plant's edible portion.

(2) The pesticidal substance is produced in the immature, but not in the mature, edible portions of the source food plant, but, in the recipient plant, the pesticidal substance is present in the mature, edible portions.

(3) The pesticidal substance is from a source food plant normally cooked or processed prior to consumption and is produced in a recipient plant that is not normally cooked or processed prior to consumption.

(4) The pesticidal substance is derived from a source food plant that is not a major crop for human dietary consumption and is introduced into a recipient plant that is a major crop for human dietary consumption.

Sexually compatible, when referring to plants, means capable of forming a viable zygote through the fusion of two gametes, including the use of bridging crosses and/or wide crosses between plants.

Source food plant means the donor of the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance.

Wide crosses, between plants, means to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre- and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures or any other technique that the Administrator determines meets this definition.

[FR Doc. 94–28823 Filed 11–22–94; 8:45 am]

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40 CFR Part 180

[OPP–300371; FRL–4755–5]

RIN 2070–AC02

Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes an exemption from the requirement of a tolerance under the Federal Food, Drug, and Cosmetic Act for residues of nucleic acids (i.e., deoxyribonucleic acid and ribonucleic acid) produced in plants as part of a plant-pesticide active or inert ingredient. Nucleic acids are ubiquitous in all forms of life, have always been present in human and domestic animal food and are not known to cause any adverse health effects when consumed as part of a food plant. Thus, EPA believes that a tolerance for nucleic

acids produced in plants is not necessary to protect the public health.

DATES: Comments identified by the docket control number [OPP–300371] must be received on or before January 23, 1995.

ADDRESSES: Submit written comments by mail to: Program Resources Section, Public Response and Program Resources Branch, Field Operations Division (7506C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the Virginia address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Bernice Slutsky, Science and Policy Staff, Office of Prevention, Pesticides and Toxic Substances (7101), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone number: (202) 260–6900.

SUPPLEMENTARY INFORMATION:

I. Introduction and Purpose of Proposed Regulation

Substances that are produced in plants to enable the plants to resist pests or disease are pesticides under FIFRA section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (i.e., if they are . . . "intended for preventing, destroying, repelling, or mitigating any pest") regardless of whether the pesticidal capabilities evolved in the plants or were introduced by breeding or through the techniques of modern biotechnology. These substances, along with the genetic material necessary to produce the substances, are designated by the Agency as "plant-pesticides."

This proposed rule would exempt nucleic acids (i.e., deoxyribonucleic acid (DNA) and ribonucleic acid (RNA)) from the requirement for a tolerance when such nucleic acids are produced in plants as part of a plant-pesticide active or inert ingredient. Nucleic acids encoding for pesticidal substances and selectable markers are considered to be part of the active and inert ingredients for plant-pesticides. Under this proposed rule, an active ingredient, when referring to plant-pesticides only, would be a "pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant." An inert ingredient, when referring to plant-pesticides only, would be "any substance, such as a selectable marker, other than the active ingredient(s), and the genetic material necessary for the production of the substance that is intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient."

Nucleic acids encoding for pesticidal substances and selectable markers are considered to be part of the active and inert ingredients for plant-pesticides for a number of reasons. First, it is the genetic material that is introduced into the plant with the intent that it will ultimately result in a pesticidal effect. Including the genetic material as part of these definitions also would permit the Agency to address the potential for the spread of the pesticidal substance in the environment through the spread of the genetic material necessary for the production of the substance. Moreover, the amount of pesticidal substance likely to be produced by the plant is also an important consideration that the Agency may, in some circumstances, be able to address through the inclusion of genetic material in the definition of plant-pesticide. In addition, including the genetic material in the definition of plant-pesticide permits the Agency to address plant-pesticides during stages of the plant's life cycle or in plant parts where the pesticidal substance itself is not produced or is produced in very small amounts (e.g., in pollen or seed).

DNA and RNA are common to all forms of life, including plants, and the Agency knows of no instance where these nucleic acids have been associated with any toxic effects related to the consumption of foods. Thus, the Agency believes that a tolerance for nucleic acids produced in plants as part of plant-pesticide active or inert ingredients is not necessary to protect the public health. The Agency is therefore proposing to exempt such nucleic acids from the requirement of a tolerance. This proposed rule is one of several proposed exemptions from the requirement of a tolerance for plant-pesticides published in today's issue of the **Federal Register**. The other proposed exemptions under FFDCA are: (1) A proposed exemption from the requirement of a tolerance for viral coat proteins ("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants"), and (2) a proposed exemption from the requirement of a tolerance for plant-pesticides that would not result in significantly different dietary exposures ("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act").

II. Statutory Authority

This exemption from the requirement of a tolerance is being proposed under the authority of section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*). The reorganization plan of 1970 reallocated the authority under FFDCA to regulate pesticide residues in foods and animal feeds to EPA. Under FFDCA section 408, pesticide chemicals added to a raw agricultural commodity, that are not "generally recognized as safe" (GRAS), are deemed to be unsafe unless a tolerance, or an exemption from the requirement of a tolerance, for such pesticide residues is established and the pesticide residue is within the tolerance limits. Section 408 of the FFDCA applies to all "pesticide chemicals" which are defined in section 201(q) of the FFDCA as:

> any substance which, alone, in chemical combination or in formulation with one or more other substance, is "a pesticide" within the meaning of [FIFRA] . . . and which is used in the production, storage, or transportation of raw agricultural commodities.

Under FFDCA section 408(c), EPA can exempt, by regulation, any pesticidal chemical from the necessity of a tolerance when such tolerance is not necessary to protect the public health. The result of such an exemption is also to authorize residues of the pesticide chemical in any processed foods made from the raw agricultural commodity that contain the residue as a result of the pesticide on the raw agricultural commodity.

III. Scientific Rationale

The Agency's proposal for exempting nucleic acids produced in plants as part of a plant-pesticide active or inert ingredient from the requirement of a tolerance is based on the ubiquity of nucleic acids and their presence in human and domestic animal food without observed adverse health effects.

Nucleic acids encode the information necessary to produce the enzymes and structural proteins essential for cellular viability. Nucleic acids are also the chemical basis for heritable traits. Once new combinations of nucleic acids are stably integrated into a plant's germ cells, these new combinations will be reproduced and be part of the genetic complement of all that plant's progeny. Thus, if the genetic information needed for production of a pesticidal substance is stably introduced into the plant, that plant and its progeny will have the potential to produce the pesticidal substance.

Chemically, the naturally occurring nucleic acids occur in two types: deoxyribonucleic acid and ribonucleic acid. DNA is a polymer of purine and pyrimidine base deoxyribonucleoside monophosphates. These individual components are called nucleotides and are commonly referred to by the different base names distinguishing them: adenine (A), cytosine (C), guanine (G), and thymine (T). The other nucleic acid, RNA, is a polymer of purine and pyrimidine base riboside monophosphates. The nucleotides are referred to by their base names also: adenine (A), cytosine (C), guanine (G), and uracil (U).

These chemicals are widespread in foods and have not, by themselves, been associated with toxic or pathogenic effects on animals or humans. None of these constituents of nucleic acids are known to be acute toxicants by themselves but, like proteins and other normal constituents of food, may cause indirect, adverse metabolic effects if consumed exclusively at high doses over a long period of time in the absence of a normal balanced diet. Nucleic acids never occur at these high amounts in food plants and have not been associated with any toxic effects related to the consumption of foods.

The Agency is aware that there are nucleic acid analogues (e.g., altered purine or pyrimidine bases) that may be considered "nucleic acids" by their chemical composition. Certain analogues are being developed as therapeutic agents for human diseases and nucleic acid analogues could conceivably be developed as pesticides. The Agency is not proposing to exempt nucleic acid analogues from the requirement for a food tolerance in this regulation. The intent of this proposal is to exempt only the naturally occurring, non-modified nucleic acids (ribosides or deoxyribosides of A, T, G, C, and U) and polymers of such substances commonly found in living cells that serve as the mechanism of encoding traits associated with pesticidal substances produced by plants.

One application of recombinant DNA technology in plants has been the introduction of DNA sequences that code for the RNA complement (anti-sense) of the messenger RNA (mRNA) for an essential enzyme or component of an obligate parasite. This RNA complement or anti-sense RNA binds the target mRNA and prevents it from binding to ribosomes, effectively terminating synthesis of the essential enzyme. This methodology is currently being developed for introducing pest-resistance into plants. It should be noted that the Agency believes that nucleic acids involved in this technology do not present a hazard to the public health and would meet the requirements for this food tolerance exemption.

The Agency has no evidence that nucleic acids by themselves present any hazard to human or domestic animal health and therefore these substances, when associated with a plant-pesticide as part of an active or inert ingredient, do not require a food tolerance to protect the public health.

IV. External Review

On July 13, 1993, a Subcommittee of EPA's Biotechnology Science Advisory Committee (BSAC) was convened to address a series of questions concerning EPA's regulatory approach under FFDCA. The BSAC Subcommittee confirmed that nucleic acids (DNA and RNA), which are present in the cells of every living organism, including plants, microorganisms and animals, used for food, do not raise safety concerns as a component of food. EPA agrees with the BSAC Subcommittee and proposes to exempt nucleic acids produced in plants from the requirement of a tolerance under FFDCA.

Based on the above information, the Agency finds that the exemption from the requirement of a tolerance established by amending 40 CFR 180.xxxx would protect the public health. Therefore, it is proposed that the tolerance exemption be established as set forth in the proposed regulatory text of this document.

V. Rulemaking Record and Procedures

Any person who has registered or submitted an application for registration of a pesticide, under FIFRA as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this proposed rule in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

EPA has established a record for this rulemaking. Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, (OPP–300371). All written comments filed in response to this proposal and the rest of the rulemaking record are available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

VI. Regulatory Requirements

The Office of Management and Budget has exempted this proposed rule from the requirement of review pursuant to Executive Order 12866.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950). This proposed rule is not subject to the Paperwork Reduction Act because it does not contain any collection of information.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Plants, Plant-pesticides, Reporting and recordkeeping requirements.

Dated: November 15, 1994.

Carol M. Browner,

Administrator.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 would continue to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. By adding § 180.1138 to read as follows:

§ 180.1138 Nucleic acids produced in plants; exemption from the requirement of a tolerance.

(a) Residues of nucleic acids produced in living plants as part of a plant-pesticide active or inert ingredient, including both deoxyribonucleic and ribonucleic acids, are exempt from the requirement of a tolerance.

(b) For the purposes of this section, the following definitions apply:

Active ingredient, when referring to plant-pesticides only, means a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

Genetic material necessary for the production means:

(1) Genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance.

(2) Regulatory regions.

It does not include noncoding, nonexpressed nucleotide sequences.

Inert ingredient, when referring to plant-pesticides only, means any substance, such as a selectable marker, other than the active ingredient, and the genetic material necessary for the production of the substance, that is intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient.

Living plant means a plant that is alive, including periods of dormancy, and all viable plant parts/organs involved in the plant's life cycle.

Noncoding, nonexpressed nucleotide sequences means the nucleotide sequences are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

Nucleic acids means ribosides or deoxyribosides of adenine, thymine, guanine, cytosine, and uracil and the polymers of these ribosides and deoxyribosides and does not apply to nucleic acid analogues.

Plant-pesticide means a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

Regulatory region means genetic material that controls the expression of the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include promoters, enhancers, and terminators.

[FR Doc. 94–28825 Filed 11–22–94; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[OPP–300367; FRL–4755–4]

RIN 2070–AC02

Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes an exemption from the requirement of a tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA) for residues of coat proteins from plant viruses when these coat proteins are produced as plant-pesticides in plants or plant parts used as raw agricultural commodities. Viral coat proteins are a specific class of pesticidal substances that can be produced in plants. These pesticidal substances, along with the genetic material necessary to produce them are designated "plant-pesticides" by EPA. EPA's proposal for exempting coat proteins from plant viruses from the requirement of a tolerance is based on virus-infected plants having always been part of the human and domestic animal food supply without detectable adverse health effects. Thus, EPA believes that a tolerance for viral coat proteins produced in plants is not necessary to protect the public health.

DATES: Comments identified by the docket control number [OPP–300367] must be received on or before January 23, 1995.

ADDRESSESS: Submit written comments by mail to : Program Resources Section, Public Response and Program Resources Branch, Field Operations Division (7506C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the Virginia address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Bernice Slutsky, Science and Policy Staff, Office of Prevention, Pesticides and Toxic Substances (7101), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone number (202) 260–6900.

SUPPLEMENTARY INFORMATION:

I. Introduction and Purpose of Proposed Regulation

Substances that are produced in plants to enable the plants to resist pests or disease are pesticides under section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (i.e., if they are . . ."intended for preventing, destroying, repelling, or mitigating any pest") regardless of whether the pesticidal capabilities evolved in the plants or were introduced by breeding or through the techniques of modern biotechnology. These substances, along with the genetic material necessary to produce the substances, are designated by the Agency as "plant-pesticides." Under this proposal a plant-pesticide would be defined as "a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant." Viral coat proteins produced in plants for viral coat protein mediated viral resistance are considered plant-pesticides because of their intended role in plant resistance to viral infection.

EPA is proposing to exempt from the requirement of a tolerance coat proteins from plant viruses when these are produced in plants for the purpose of protecting plants against viral disease. Because of the characteristics of viral coat proteins, the Agency does not believe that a tolerance for these pesticidal substances is necessary to protect the public health.

This proposed rule is one of several proposed exemptions from the requirement of a tolerance for plant-pesticides published in today's issue of the **Federal Register**. The other proposed exemptions under FFDCA are: (1) A proposed exemption from the requirement of a tolerance for nucleic acids in plants ("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants," and (2) a proposed exemption from the requirement of a tolerance for plant-pesticides that will not result in significantly different dietary exposures

("Plant-pesticides; Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act."

II. Statutory Authority

This exemption from the requirement of a tolerance is being proposed under the authority of section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321 *et seq.*). The reorganization plan of 1970 reallocated the authority under FFDCA to regulate pesticide residues in foods and animal feeds to EPA. Under FFDCA section 408, pesticide chemicals added to a raw agricultural commodity, that are not "generally recognized as safe" (GRAS), are deemed to be unsafe unless a tolerance, or an exemption from the requirement of a tolerance, for such pesticide residues is established and the pesticide residue is within the tolerance limits. Section 408 of the FFDCA applies to all "pesticide chemicals" which are defined in section 201(q) of the FFDCA as:

> any substance which, alone, in chemical combination or in formulation with one or more other substance, is "a pesticide" within the meaning of [FIFRA] ... and which is used in the production, storage, or transportation of raw agricultural commodities.

Under FFDCA section 408(c) EPA can exempt, by regulation, any pesticidal chemical from the necessity of a tolerance when such tolerance is not necessary to protect the public health. The result of such an exemption is also to authorize residues of the pesticide chemical in any processed foods made from the raw agricultural commodity that contain the residue as a result of the pesticide on the raw agricultural commodity.

III. Scientific Rationale

A. Summary

Coat proteins are those substances that viruses produce to encapsulate and protect their genetic material. When the genetic material encoding for the coat protein is introduced into a plant's genome, the plant is able to resist infections by the virus donating the genetic material for the coat protein (as well as strains closely related to the donor virus). This resistance is termed viral coat protein mediated resistance or vcp-mediated resistance.

EPA's rationale for finding that a tolerance for viral coat proteins in foods is not necessary to protect the public health rests on the points discussed in this preamble. These points are: (1) Virus-infected plants have always been a part of the human and domestic animal food supply since most crops are frequently infected with plant viruses and food from these crops have been and are being consumed without detectable adverse human health effects. (2) Plant viruses have never been shown to be infectious to humans or mammals. Plant viruses are not able to replicate in mammals or other vertebrates, limiting the possibility of human infection. In addition, this exemption applies only to the portion of the viral genome coding for the whole coat protein or a subcomponent of the coat protein which will be expressed in the plant during viral coat protein mediated resistance. This portion by itself is incapable of forming infectious particles. Since whole, intact plant viruses are not known to cause deleterious human health effects, it is reasonable to assume that a subunit of these viruses likewise will not cause adverse human health effects.

B. Presence in Food Supply and Inability to Replicate in Vertebrates

Entire infectious particles of the plant pathogenic virus, including the coat protein component, have been and are being consumed by humans with no observed adverse effects. Virus-infected food plants have always been a part of the human and domestic animal food supply (Refs. 1, 6, and 7). At the beginning of this century virtually every commercial cultivar of potatoes grown in the United States and Europe was infected with either one or some complex of potato viruses (Ref. 1).

All plants have viruses that can infect them. While some viruses may be limited to certain tissues (e.g., the vascular system) or organs (e.g., roots), most plant viruses are found throughout the various organs and tissues of plants. Viruses, including the coat protein component, are found in the fruit, leaves, and stems of most plants. The long history of inadvertent mammalian consumption of the entire plant virus particle in foods with no observed ill effects presents a strong argument to support the human and domestic animal safety of the entire virus in foods.

Concentrations of the virus particles in infected plants vary widely according to the host plant, length of infection, and the reproductive life cycle of the virus itself. Current crop varieties bred for virus resistance are usually tolerant to virus infection rather than actually being resistant or immune to infection, i.e., they do not express gross disease symptoms even though these resistant varieties can contain concentrations of virus similar to susceptible varieties (Ref. 5). The levels of virus in virus-infected plants can be as high as 0.1 to 0.3 mg/gm tissue as seen with Tobacco Mosaic Virus (Ref. 5). The total amount of virus particles, including the coat protein component, in naturally infected plants can often be several orders of magnitude higher than the concentration expected for viral coat proteins expressed as plant-pesticides. Plants modified to be virus resistant through viral coat protein mediated resistance generally express coat proteins from plant viruses at concentrations two to three orders of magnitude lower than plants naturally infected by viruses (Ref. 6). Thus, consumers could be exposed to less coat protein through plants expressing coat proteins than through virus-infected crops. However, the average amount of coat protein a consumer might ingest in food from a virus susceptible crop could, in some instances, be less than the average amount present in food from plants protected from virus infection through the production of viral coat proteins since food from the virus susceptible crop might be derived from both virus-free and virus-infected plants. In general, though, EPA anticipates that the amounts of viral coat protein consumed in the diet due to the production of viral coat proteins in vcp-mediated resistance will be similar to the amounts of viral coat proteins currently consumed.

Plant pathogenic viruses have never been shown capable of infecting or replicating in vertebrates (Refs. 2, 3, 4, and 5). Intact, infectious, whole plant viruses, therefore, are not infectious to humans. Given that the complete virus is not infectious to vertebrates, it is reasonable to assume that a noninfectious subcomponent of the virus would not be hazardous to humans or animals. Purified preparations of plant viruses have routinely been handled by researchers without specialized protection of workers (researchers) against infection. These purified plant virus preparations are also frequently injected into laboratory animals for the production of specific antibodies without any adverse effects to the animals. No specific toxicological testing of purified plant virus preparations has been reported in the literature.

IV. External Review

In developing its regulatory approach for plant-pesticides, EPA requested the advice of a Subpanel of the FIFRA Scientific Advisory Panel (SAP). On December 18, 1992, the SAP Subpanel was convened to review a draft policy statement for plant-pesticides and respond to a series of scientific questions posed by the Agency.

One question that the Agency asked the SAP Subpanel was whether coat proteins from plant viruses might present a dietary risk. In answer to the question the Subpanel stated that "[s]ince viruses are ubiquitous in the agricultural environment at levels higher than will be present in transgenic plants, and there has been a long history of 'contamination' of the food supply by virus coat protein, there is [a] scientific rationale for exempting transgenic plants expressing virus coat protein from the requirement of a tolerance." EPA agrees with this position and is proposing an exemption from the requirement of a tolerance for coat proteins from plant viruses when produced in plants.

Based on the information presented in this document, EPA finds that a tolerance for viral coat proteins produced in plants is not necessary to protect the public health. Thus, it is proposed that an exemption from the requirement of a tolerance be established by amending 40 CFR part 180 as set forth in the regulatory text of this document.

V. Rulemaking Record and Procedure

Any person who has registered or submitted an application for registration of a pesticide, under FIFRA as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this proposed rule in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

EPA has established a record for this rulemaking. Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, (OPP–300367). All written comments filed in response to this proposal and the rest of the rulemaking record will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

VI. Regulatory Requirements

The Office of Management and Budget has exempted this proposed rule from the requirement of review pursuant to Executive Order 12866.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950). This proposed rule is not subject to the Paperwork Reduction Act because it does not contain any collection of information.

VII. References

(1) Beemster, A.B.R. and J.A. de Bokx. 1987. Survey of Properties and Symptoms of Potato Viruses, pp. 84–93 In: Viruses of Potatoes and Seed Potato Production; J.A. de Bokx and J.P.H. vanderWant. PuDOC, Wageningen, The Netherlands.

(2) Brun, G. 1991. "Rhabdoviridae". Chap. 17, pp. 443–460; In: Atlas of Invertebrate Viruses eds. J.R. Adams and J.R. Bonami. CRC Press, Boca Raton, FL.

(3) EPA Issue Paper. Issues associated with the regulation of viral coat proteins under FIFRA and FFDCA.

(4) Gibbs, A. and B. Harrison. 1976. Plant Virology: The Principles, Chap. 1. J. Wiley Sons, New York.

(5) Matthews, R.E.F. 1981. Plant Virology. Chaps. 12, 16, and 19. Second edition, Academic Press, New York.

(6) Palukaitis, P. 1991. Virus-mediated genetic transfer in plants. In: Risk Assessment in Genetic Engineering. Edited by M.A. Levin and H.S. Strauss. McGraw-Hill, Inc., New York. pp. 140–161.

(7) Provvidenti, R., R.W. Robinson, and H.M. Munger. 1984. Occurance of Zucchini Yellow Mosaic Virus in Curcubits from Connecticut, New York, Florida and California, Plant Disease 68:443–446.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Plants, Plant-pesticides, Reporting and recordkeeping requirements.

Dated: November 15, 1994.

Carol M. Browner,

Administrator.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 would continue to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. By adding § 180.1136 to read as follows:

§ 180.1136 Viral coat proteins used as plant-pesticides; exemption from the requirement of a tolerance.

(a) Residues of coat proteins from plant viruses, or segments of the coat proteins, produced in living plants as plant-pesticides are exempt from the requirement of a tolerance.

(b) For the purpose of this section, the following definitions apply:

Genetic material necessary for the production means:

(1) Genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance.

(2) Regulatory regions.

It does not include noncoding, nonexpressed nucleotide sequences.

Living plant means a plant that is alive, including periods of dormancy, and all viable plant parts/organs involved in the plant's life cycle.

Noncoding, nonexpressed nucleotide sequences means the nucleotide sequences are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

Plant-pesticide means a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.

Regulatory region means genetic material that controls the expression of the genetic material that encodes for a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include promoters, enhancers, and terminators.

[FR Doc. 94–28824 Filed 11–22–94; 8:45 am]

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federal register

Wednesday
November 23, 1994

Part V

Department of the Interior

Fish and Wildlife Service

50 CFR Part 20

Migratory Bird Hunting; Notice Concerning the Proposal for Conditional Approval of Bismuth-Tin Shot as Nontoxic for the 1994–95 Seasons; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018—AC66

Migratory Bird Hunting; Notice Concerning the Proposal for Conditional Approval of Bismuth-Tin Shot as Nontoxic for the 1994–95 Seasons

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of the status of Fish and Wildlife Service consideration of the use of bismuth-tin as nontoxic shot for migratory bird hunting.

SUMMARY: The U.S. Fish and Wildlife Service (Service) is notifying the public that bismuth-tin is not conditionally approved at this time for the 1994–1995 migratory bird hunting season. Initial studies to determine the toxicity of bismuth-tin shot have not been completed. A decision on conditional interim approval will not be made until these initial studies are completed.

FOR FURTHER INFORMATION CONTACT: Paul R. Schmidt, Chief or Keith Morehouse, Staff Specialist, Office of Migratory Bird Management (MBMO), U.S. Fish and Wildlife Service, 634 ARLSQ, 1849 C St. NW, Washington, D.C. 20240 (703/358–1714).

SUPPLEMENTARY INFORMATION: The Service published a proposed regulation on August 22, 1994 (59 FR 43088) to provide for conditional interim approval of bismuth-tin shot as nontoxic for the 1994–1995 migratory bird hunting season. This proposed regulation was developed as a result of evidence provided in a petition for rulemaking from the Bismuth Cartridge Company of June 14, 1994 that this product has a high probability of being nontoxic. The petition requested that the Service modify the provisions of 50 CFR 20.21(j), to legalize the use of bismuth-tin shot on an interim, conditional basis for both the 1994–95 and the 1995–96 seasons, based upon some scientific evidence (outside of the testing procedures required by regulation) and use indicating the product is environmentally safe. This petition acknowledged responsibility by the Bismuth Cartridge Company to complete the nontoxic shot approval procedure studies as outlined in 50 CFR 20.134. The proposed rule stated that a final decision on the status of bismuth-tin as nontoxic would be held in abeyance pending completion of all three tests of the bismuth-tin toxicity studies.

The toxicity analysis procedures (50 CFR 20.134) consist of three tests which represent the three major categories of toxic effects: Short-term periodic exposure, chronic exposure under adverse environmental conditions, and chronic exposure impact on reproduction. Tests include both steel shot and lead shot control groups with statistical analyses performed on all data from each test. Test 1 is a short-term, 30 day acute toxicity study using commercially available duck food and includes blood testing and organ analysis. Test 2 is a chronic 14 week toxicity test in cold weather using a nutritionally-deficient diet and test 3 is a chronic dosage study that includes reproductive assessment using a commercially available duck food diet.

To conduct the 30-day (short-term) acute toxicity study, the Bismuth Cartridge Company contracted with Dr. Glen Sanderson, Center of Wildlife Ecology, Illinois Natural History Survey. As of September 21, 1994 (close of the comment period for the proposed rule) Dr. Sanderson had completed the dosage and preliminary analysis portion of test 1 with no mortality reported; however, other required examination and analyses (also a part of test 1) were yet to be completed. As provided in the proposal for interim approval, published August 22, 1994, "* * * this concluding work will be completed before any final rulemaking * * *" As of November 4, 1994, the Service has not received the requisite test results.

The August 22 proposed rule invited comments from interested parties. Closing date for receipt of all comments was September 21, 1994. During this 30-day comment period, the Service received a total of 351 comments. These comments consisted of 2 from Flyway Councils, 5 from Federal Agencies, 19 from State fish and wildlife agencies, 23 from other organizations, and 302 from individuals, including a letter signed by 33 Congressmen.

These comments have provided insight into a wide range of issues that deserve careful review; however, MBMO considers toxicity testing as the key component in the immediate resolution of this issue and the development of a Service position. Regulations (50 CFR 20.134) clearly describe the procedure to be used for approving shot as nontoxic. There is a body of evidence (outside the tests required by regulation) that indicates the product is likely to be nontoxic and will be confirmed as such during the testing process. However, in the current on-going toxicity testing, even the first test of the three test sequence has not been completed and for the Service to provide conditional approval for the use of bismuth-tin as nontoxic shot, at this time, would be ill-advised.

The analyses are incomplete and a definitive, scientifically supported test result and full report that proves the nontoxicity of bismuth-tin is presently unavailable. A final determination on the status of bismuth-tin will be made by the Service within 2 weeks of receipt of this report. Pending completion and review of this ongoing testing, the Service is unable to conditionally approve the use of bismuth-tin shot at this time. Therefore pursuant to 50 CFR 20.21(j), Hunting Methods, steel shot is the only nontoxic shot approved for use in hunting waterfowl. In the meantime, testing will continue and results will be evaluated as they become available. Following receipt of the test results, the Service will make a decision on conditional interim approval.

Dated: November 16, 1994.

George T. Frampton, Jr.,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 94–28940 Filed 11–22–94; 8:45 am]

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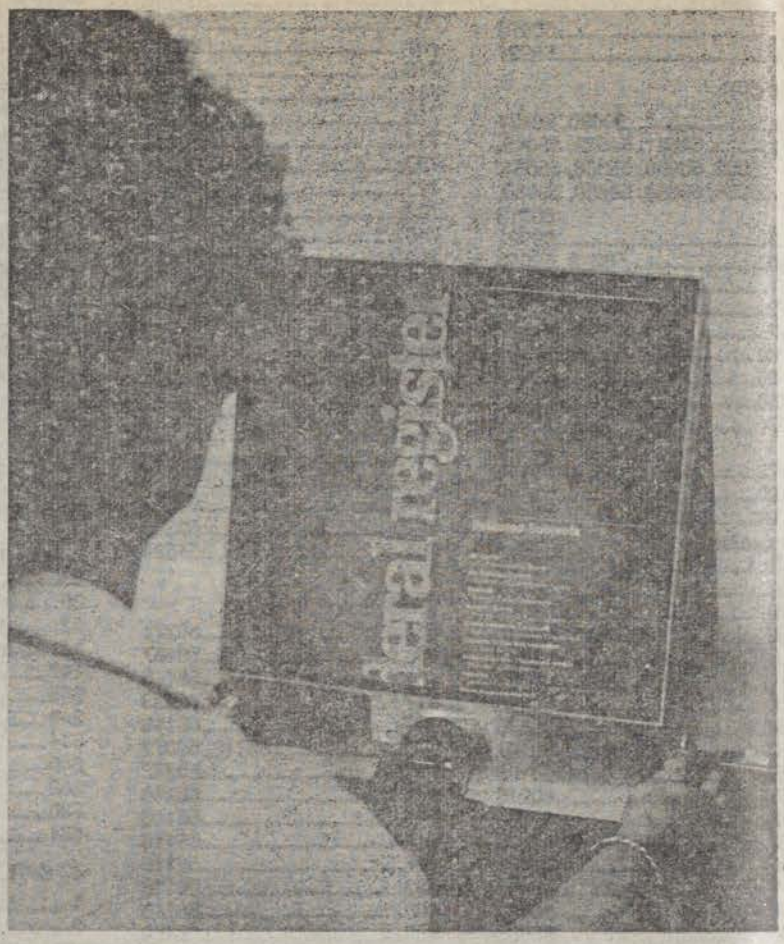

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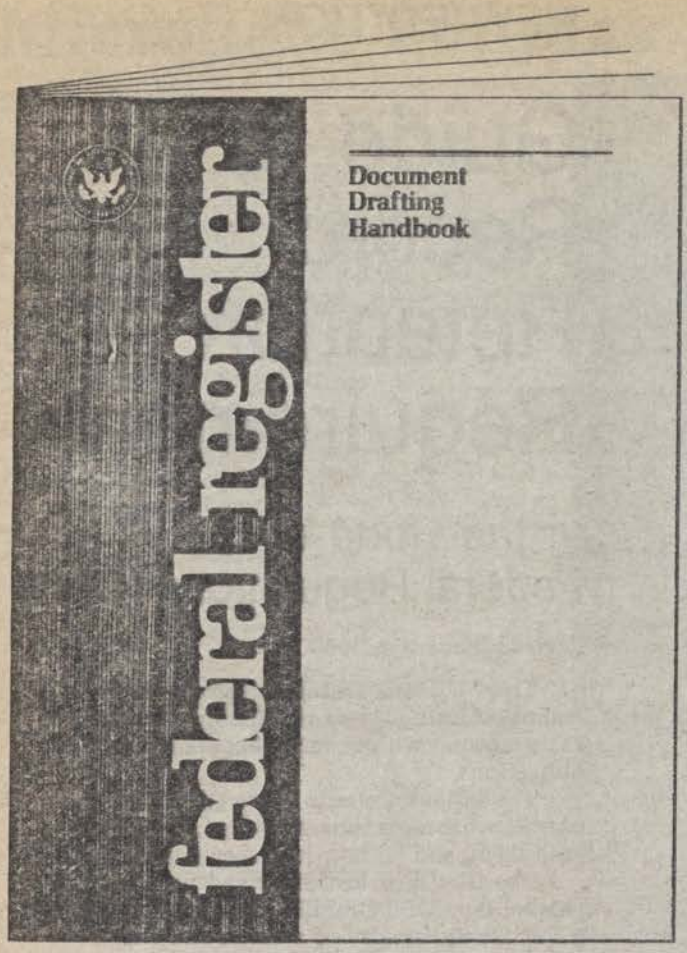

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